1981 End-Stage Renal Disease

Annual Report To Congress

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Health Care Financing Administration

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ESRD ANNUAL REPORT TO CONGRESS

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EXECUTIVE SUMMARY

The Health Care Financing Administration (HCFA) was established to combine health financing and quality assurance programs into a single agency. HCFA is responsible for the Medicare program, Federal participation in the Medicaid program, the Professional Standards Review program and a variety of other health care quality assurance programs.

The mission of the Health Care Financing Administration is to promote the timely delivery of appropriate, quality health care to its beneficiaries-approximately 47 million of the nation's aged, disabled and poor. The Agency must also ensure that program beneficiaries are aware of the services for which they are eligible, that those services are accessible and of high quality and that Agency policies and actions promote efficiency and quality within the total health care delivery system.

The End-Stage Renal Disease (ESRD) Annual Report to Congress is prepared in accordance with Section 1881(g) of the Social Security Act. It is the third in a series of annual reports prepared by HCFA to assess the implementation and effectiveness of the ESRD program.

The report covers the full range of activities related to the care of ESRD patients that took place during 1980. This includes the number of patients utilizing the various forms of treatment and discussions of cost savings experiments and basic kidney research conducted during the year. The report is divided into nine chapters: Overview, Data Collection, Dialysis, Transplants, Mortality and Morbidity, Costs, Research, Network Activities and Five-Year Projections.

The data collected for the report showed that 1980 was a year of substantial growth in the ESRD dialysis population. The total dialysis population increased from 45,394 patients to 52,364 patients, a 15.4 percent increase. The home dialysis population increased from 5,968 patients to 7,661 patients, a 28.4 percent increase. The total number of patients transplanted increased from 4,152 to 4,671, an increase of 12.5 percent.

Total expenditures for services rendered during 1980 were $1.1 billion, up from $992.2 million in 1979. The 1980 figure will probably increase, however, as bills continue to be posted. The average payment rate for a dialysis session was $148, excluding physicians' fees. Kidney transplantation charges averaged $20,156, an increase of 4.4 percent over 1979. In summary, the data showed increased use of the treatment modalities that Congress wished to emphasize and cost increases at a rate well below the general medical care inflation rate.

During 1980 the ESRD program was the responsibility of the Office of End-Stage Renal Disease (ESRD) in the Office of Special Program (OSP), HCFA. In November 1981, OESRD and OSP were abolished and their responsibilities were allocated back to the appropriate HCFA functional component. The bulk of this report was prepared by the OSP before it was abolished. The responsibility for this report has now been transferred to the Office of Coverage Policy (OCP), Bureau of Program Policy (BPP), HCFA.

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OVERVIEW

INTRODUCTION

The End-Stage Renal Disease (ESRD) Program is administered by the Health Care Financing Administration (HCFA) in the Department of Health and Human Services. Eight years have elapsed since Congress first authorized funding for the End-Stage Renal Disease program. In the enacting statute, as well as in subsequent legislation, Congress clearly articulated the mission of the ESRD program: to assure patient access to high quality, cost effective medical care. The ESRD program, in keeping with Congressional intent, has established the following goals and objectives to assist in carrying out its mission:

- To ensure that beneficiaries who have been diagnosed as having end-stage renal disease receive the care they need;
- To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;
- To provide for the efficient delivery of appropriate care by physicians and facilities; and
- To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

Major strides have been made in achieving these goals. The report which follows documents this progress in accordance with the annual reporting requirements of P.L. 95-292.

The overview is divided into two sections. The first section Program Highlights, indicates the direction in which the program moved during 1980, and highlights areas of special significance or improvement. The second section, Program Activities, presents a brief summary of 1980 activities of interest to Congress and the ESRD community; activities which are discussed in greater detail in the body of this report.

PROGRAM HIGHLIGHTS

- The total dialysis population increased by 15.4 percent, to 52,364 from 45,394 in 1979.

- The home dialysis population increased by 28.4 percent, to 7,661 from 5,968 in 1979.

- The number of patients receiving a transplant increased by 12.5 percent, to 4,671 from 4,153 in 1979.

- At the end of 1980, the home dialysis population accounted for 14.6 percent of the total dialysis population, a net increase of 1.5 percent over 1979.

- The home dialysis population within networks ranged from 5.2 percent to 45.1 percent. Twenty-three networks showed a net increase over 1979 in the percentage of patients treated at home, 8 showed decreases, and 1 showed no change.

Patients transplanted in 1980 accounted for 8.2 percent of the total ESRD population, a net decrease of 0.2 percent over 1979.

  - Patients transplanted in 1980 ranged from 2.5 percent to 23.8 percent of the total ESRD population in each network. Ten networks showed a net increase over 1979 in the percentage of ESRD patients transplanted, 19 showed decreases, and 3 showed no change.

- The net increase in home patients was due largely to shifts of patients from an in-center setting to home. For 1980, 71 percent of the increase was due to shifts, as compared to 47 percent in 1979.

  - This trend is largely attributable to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 465 patients in 1979 to 2,334 patients in 1980. CAPD now accounts for 30 percent of all home patients.

- The percentage of total transplants performed with kidneys from living related donors continued to decline, to 27.1 percent from 28.3 percent in 1979.

- The average kidney acquisition charge in 1980 was $7,581 for a living related donor kidney and $6,992 for a cadaveric kidney. The average estimated costs were $6,271 and $5,788 respectively.

- The age, race, and sex adjusted mortality rate for all ESRD patients included in a specific study population was 122.9 per 1,000. Survival was poorest in the first year, and improved 1-2 percent each successive year up to year 6, the last year the population was studied.

- Payment rates for dialysis averaged $148 per treatment without physician fees. This figure represents payments to both hospital and freestanding dialysis units for infacility treatments.

- The average charge for a transplant was $20,156 in 1980, up 4.4 percent from $19,300 in 1979.

- Total program expenditures for services rendered during 1980 were $1.1 billion, based on bills posted as of March 30, 1981.

PROGRAM ACTIVITIES

During 1980, the ESRD program progressed toward achievement of its stated goals, primarily by improving current operating procedures and by completing implementation of the provisions enacted in P.L. 95-292. Efforts were particularly rigorous in the areas of ensuring patient access to care, including fostering educational efforts on choice of treatment modality, and improving data, including emphasizing increased reporting compliance and reducing the reporting burden associated with the ESRD Medical Information System.

Research and evaluation activities were also strong in 1980. A comprehensive evaluation plan was developed for the ESRD program which includes issues of quality, access, and cost containment. The section on Cost Savings Experiments contains a full explanation of the development of the evaluation plan. Two areas of research were discussed at length with the renal community: the safety, efficacy, and cost effectiveness of dialyzer reuse, and the need for research funding, in the areas of kidney transplantation and dialysis techniques.

Overall, 1980 was a year of high visibility for the ESRD program. In addition to many small scale studies and investigations by both federal and non-federal entities, formal program investigations and audits were initiated by the General Accounting Office and the Inspector General's Office. These investigations focused primarily on patient rehabilitation activities and program costs.

The sections which follow provide an overview of these and other program activities in the areas of patients, data, and oversight.

Patients

Major program efforts in this area focused on the placement of patients in the most appropriate treatment modality. In particular, the program worked to meet the Congressionally mandated goal of encouraging self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

Debate continues within the government and the renal community as to what the maximum number should be. HCFA commissioned a small scale survey of eight ESRD Network Coordinating Councils to determine what criteria could be used to select patients for these treatment modalities. The study revealed general agreement that the following factors would probably prohibit a certain number of patients from choosing either home dialysis or transplant.

CRITERIA FOR PATIENTS NOT SUITABLE FOR HOME DIALYSIS

1. The patient does not have a "willing" or "suitable" partner to assist with home dialysis. (Not applicable to Continuous Ambulatory Peritoneal Dialysis.)
2. The patient does not have "adequate space or facilities" at home for dialysis. (Not applicable to Continuous Ambulatory Peritoneal Dialysis.)
3. The patient has an "unstable medical condition."
4. The patient is scheduled for a living related donor transplant within the next 6 months.
5. A physician has "disapproved" the patient as a candidate for other reasons.

CRITERIA FOR PATIENTS NOT SUITABLE FOR TRANSPLANTATION

1. The patient is over 55 years old.
2. There is a note by a physician indicating a contraindication, such as uncontrolled hypertension.
3. A contraindication is specified by the transplant surgeon to whom the patient is referred.
4. The patient has been informed of the risks of transplantation and refuses to consent to surgery.

While precise data on the numbers of patients in the above categories are not available, we can approximate a large portion of this population. Medicare enrollment data for December 1980, indicate that of the total, currently entitled ESRD population, 32 percent are entitled to disability benefits (for any reason) and 20 percent are retirement insurance beneficiaries (age 65 or older). This population represents the bulk of those patients who are unsuitable for home dialysis or transplantation.

It is estimated that only 20 percent of the disabled and 10 percent of the aged would be suitable for these treatment modalities. After a downward adjustment to remove from consideration the aged and disabled patients who are not considered appropriate for these therapies, an optimum home dialysis and transplantation population of 56.4 percent of the total ESRD population is estimated. Adjusting the 1980 pool of home dialysis or transplant candidates by using these assumptions reveals that although 22.8 percent of the total ESRD population were treated by either of these two modalities during 1980, they represent 38.3 percent of the pool of eligible candidates for either home dialysis or transplant.

Traditionally, it is believed that patients who have been treated in an in-center setting for any length of time are reluctant to transfer to a home setting. However, an analysis of the net increase of dialysis patients treated in the home reveals that a relatively new treatment, continuous ambulatory peritoneal dialysis (CAPD), may be challenging that assumption. CAPD was approved for Medicare reimbursement on September 15, 1979. Seventy-one percent of the 1980 net increase in home patients was due to shifts from an in-center setting. This contrasts sharply to a comparable figure of 47 percent in 1979. Much of this shift may be attributable to the rapid growth of CAPD in 1980, which added about 200 patients per month to the ESRD home patient roles. CAPD appears to offer both the patient and the program significant advantages. From a patient's point of view, these include freedom from a machine, less restrictive dietary requirements, and elimination of the need for a home helper. From the ESRD program's perspective, CAPD appears to be a relatively inexpensive form of treatment.

CAPD also influenced the number of patients completing a self-care training course. This figure increased from 3,250 in 1979 to 5,010 in 1980. Most of this increase occurred due to the 2,293 CAPD patients who completed training in 1980. These figures raise some questions about the effectiveness of some self-care training programs. The 5,010 patients who completed training led to an increase of only 1,854 in total patients on self-care at the end of 1980. Although some of this discrepancy is due to deaths, or patients leaving home dialysis for other forms of treatment, there is still some number of patients who complete self-care training, but do not dialyze in a self-care setting.

Preliminary investigations reveal that comprehensive follow-up and back-up resources are critical to prevent high drop out rates among home patients. Larger home training programs appear to have higher success rates than smaller centers, i.e., those which train only 4 or 5 patients per year. HCFA has initiated a comprehensive study in this area.

The number of patients transplanted in 1980 was 4,671 versus 4,153 in 1979. This represents an increase of about 12.5 percent, but it is important to note that this rate is less than the 15.4 percent reported rate of growth of the total ESRD population. If this signals the beginning of a trend which might lead to an increasingly smaller proportion of the ESRD population being transplanted, it is important to determine the causative factors. According to an analysis by the American Society of Transplant Surgeons, although transplantation is expensive, a successful transplant is much more cost effective than years of in-center dialysis.

Preliminary analysis shows that there are several possible factors which might have a negative effect on transplants. The first is a shortage of cadaveric kidneys available for transplantation. However, it is not known to what extent this may be a factor. Twenty percent of all kidneys harvested in 1980 were not used, but it is impossible to tell how many of those kidneys were discarded as non-viable malfunctioning, or actually suitable for transplant but discarded due to lack of availability of a suitable recipient. Further discussion on cadaveric kidneys is contained in the section on Patients Awaiting Organs. Another reason might be the lack of firm patient information on the pros and cons of transplantation, including graft failure and mortality rates for transplant patients. Some patients may be hesitant to choose transplantation without this information.

Data

The ESRD Medical Information System (MIS) was created to establish a uniform data base of national scope, to contain medical and management data elements related to the services provided by ESRD facilities and the treatment of dialysis and transplant patients. These data are used to monitor the ESRD program in a variety of ways, from providing reimbursement data for audits to providing patient treatment data for research purposes.

The MIS contains subsystems which provide a comprehensive range of data on all aspects of the ESRD program. These subsystems include data related to mortality and survival, incidence and prevalence, treatment practices, distribution of facilities and other resources, actuarial projections on program growth, and costs of treatments. However, in the past due to longstanding problems with incomplete reporting, much of this information is not complete, and therefore, has not been reported to Congress. In recognition of the importance of good data to efficient and effective management of an increasingly complex program, HCFA made the improvement of the ESRD MIS one of its major initiatives during 1980.

The Networks are validating the data from a network perspective to ensure their reasonableness. However, the data have not actually been verified by checking them against the actual facility records used to complete the required MIS forms. HCFA will begin to conduct comprehensive validation studies by sampling a percentage of forms to be checked against the original medical records. Also, unaudited data in the present cost analysis system will be checked against the results of audits conducted to establish an incentive reimbursement rate.

Several additional activities were begun in 1980 to allow more comprehensive reporting of program progress to Congress. Steps were initiated to compile certain data elements on an individual patient basis. All patient data is now reported on an aggregate basis. This allows monitoring of gross changes in the ESRD population from the beginning to the end of a given calendar year, but does not permit analysis of all intermediate transfers which take place during the year. For example, it is impossible to determine the number of patients who shift from in-center dialyisis to self-care training and home dialysis during the year, but return to in-center dialysis by the year's end. Access to this type of information would permit better analysis of such diverse activities as failure rates of self-care training programs.

The development of an individual patient census is proceeding concurrently with the development of a minimum data set which will provide faster feedback on a number of critical factors relating to patient treatment. In this regard, patient profile tables will be available for national distribution. The development of these tables and other data analyses will permit HCFA to respond quickly to special requests.

A final activity included consolidation of a number of forms to reduce the reporting burden on ESRD facilities. Six hundred thousand outpatient dialysis supplemental forms will be eliminated by incorporating critical data elements onto the Medicare outpatient bill. In addition, patient diagnostic information will no longer be collected on a separate Patient History form, but will instead be incorporated onto the required Medicare entitlement form. This activity will have two distinct advantages in addition to reducing the reporting burden on facilities. First, compliance will increase from 50 percent to almost 100 percent since this form is required for Medicare entitlement. Second, the patient data reported should be more reliable, since the medical evidence portion of the entitlement form requires a renal physician's signature.

OVERSIGHT

One major review of the ESRD program in 1980 was a Service Delivery Assessment conducted by the Inspector General on patient attitudes. This report focused exclusively on patients and represents the first formal documentation of patient concerns. Several significant recommendations of the report and HCFA's response follow.

The report recommended upgrading the practice of patient education to familiarize patients with each treatment option available to them. During 1980, the ESRD program sponsored a number of activities designed to carry out this recommendation. Slide presentations for patients were prepared on transplantation and self-dialysis. A comprehensive self-care training manual was developed to assist patients choosing this modality of care. Work began on an ESRD Program Overview document for patients, covering all aspects of the ESRD program. Some Networks conducted workshops for patients, as well as for the professionals involved in referring patients to different treatment modalities. Many directed additional resources to their patient advisory committees in an effort to be more responsive to patient concerns. Others focused their activities on developing agreements with State Vocational Rehabilitation Agencies to encourage employment opportunities for ESRD patients.

A related recommendation in the report concerned the patient assessment process. Current regulations require each ESRD facility to evaluate each patient at least every 12 months for the appropriate treatment setting. HCFA supported the development of a patient care planning manual based on the use of a "whole life" record keeping system. This system was designed to assist facilities and physicians in this patient care planning process. This system stresses patient goals in the medical status, as well as social and rehabilitative status, and includes strategies to be used by professionals in assisting the patient toward achievement of these goals. Other recommendations focused on the promotion of self-care opportunities, particularly at home. The program's activities in this area have been described previously in the patient section of this overview.

One additional major oversight activity was initiated in 1980: a study by the General Accounting Office (GAO) on the costs of home dialysis. The report has not yet been completed, but it is expected to provide very useful information on the cost of home dialysis. Other information on the benefits of home dialysis and in-center dialysis in terms of patient status, such as employability, will be available from a two year grant awarded by HCFA in 1980 to Battelle Memorial Institute to study the outcomes of all treatment modalities.

Smaller scale studies conducted by the Department in 1980 looked at physician reimbursement for supervisory services, billing for laboratory services, and conflict of interest in Network decision making related to planning/determination of need. Most of these studies were only pre-tests of larger scale studies to be conducted in 1981. The results will be provided as they become available.

DATA COLLECTION

DATA COLLECTION

All information concerning the numbers of patients in the various treatment modalities, and the number of transplants performed, was gathered through use of a data collection form known as the End-Stage Renal Disease Facility Survey. For 1980, the Facility Survey was distributed twice, the first time to cover the first six months of calendar year 1980, and the second time to cover the last six months of the year. In previous years the Facility Survey was distributed on an annual basis. A copy of the most recently issued Facility Survey form and instructions for its completion are included in Appendix E.

A total of 1,027 facilities which perform some form of maintenance dialysis, and 149 hospitals which perform kidney transplants, were requested to complete a Facility Survey. The rate of compliance with that request was 100 percent.

The number of facilities surveyed does not equal the total number of ESRD certified facilities in the country. Two transplant hospitals were excluded from consideration because they voluntarily stopped performing transplants before January 1, 1980. Some other ESRD hospitals were excluded from consideration because they provide only backup dialysis on an acute basis, rather than routine maintenance dialysis. Other facilities were not requested to complete a Facility Survey because they were so recently certified there was not sufficient time to include them in the survey population.

The data reported via the Facility Survey delineates totals for all patients with end-stage renal disease. That is, the data are not differentiated between patients who have attained entitlement to Medicare benefits and those who have not, within the various treatment modalities. The decision to gather and report data on a total patient basis rather than on a Medicare patient basis was made in recognition of the fact that the ESRD Annual Report to Congress is the only national report made that deals with end-stage renal disease.

Collecting and reporting data on a total patient basis was begun for last year's Annual Report, which covered calendar year 1979. Prior to that data was collected and reported only on Medicare beneficiaries. Last year's Annual Report showed sharp increases in all patient population classifications. A large portion of those increases was caused by including non-Medicare patients in the data base.

Although we have no data to definitely indicate what portion of the patients in any particular treatment modality were recipients of Medicare benefits, we know through the Facility Survey that at the end of 1980, 85.6 percent of all patients were entitled to Medicare benefits, 7.3 percent had applications for Medicare entitlement pending, and 7.1 percent were not Medicare eligible. Since Medicare entitlement is invariably granted retroactively, entitlement can only be granted after all eligibility requirements have been met, we can infer that, for services rendered on any given day, Medicare will make reimbursement for over 85 percent of the patients and that ultimately 93 percent of the patients will receive some Medicare reimbursement. In making comparisons between the 1980 data presented in this report and the data from the previous year, the 1979 data is not necessarily that which was reported in last year's Annual Report. Rather, we have used updated 1979 data where available.

TABLE 1

ESRD FACILITIES SURVEYED AND REPORTING

ESRD	DIALYSIS	FACILITY	TRANSPLANT	FACILITY
Network	Surveyed	Reporting	Surveyed	Reporting
1	7	7	1	1
2	23	23	4	4
3	44	44	3	3
4	83	83	11	11
5	20	20	3	3
6	24	24	4	4
7	25	25	3	3
8	17	17	2	2
9	26	26	8	8
10	30	30	5	5
11	64	64	6	6
12	27	27	5	5
13	20	20	2	2
14	33	33	11	11
15	58	58	7	7
16	12	12	3	3
17	22	22	6	6
18	50	50	4	4
19	57	57	4	4
20	40	40	4	4
21	17	17	4	4
22	37	37	6	6
23	21	21	5	5
24	52	52	5	5
25	57	57	6	6
26	22	22	5	5
27	14	14	2	2
28	32	32	9	9
29	14	14	1	1
30	41	41	4	4
31	13	13	3	3
32	25	25	3	3
TOTAL	1,027	1,027	149	149

DIALYSIS*

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*Material in this section responds to:

Section 1881(g)(1) "the number of patients nationally and by renal disease network on dialysis (self-dialysis or otherwise) at home and in facilities"

Section 1881(g)(2) "the number of new patients entering dialysis at home and in facilities during the year"

Section 1881(g)(3) "the number of facilities providing dialysis and the utilization rates of those facilities"

PATIENT PROFILE

Total Dialysis Population

As of December 31, 1980, the total dialysis population was 52,364. The ESRD Networks' total dialysis populations range in size from 374 patients to 4,080 dialysis patients. However, the 10 largest Networks contain approximately 55 percent of the total dialysis population.

In-Center Dialysis Population

The number of patients receiving their treatments in facilities was 44,703 at the end of 1980. This represents 85.3 percent of the total dialysis population. The ESRD Networks range in size from 308 in-center dialysis patients to 3,831 in-center dialysis patients. Of the in-center population, 43,401, or 97.1 percent, were receiving staff-assisted outpatient maintenance dialysis, 781, or 1.7 percent were performing in-center self-dialysis, and 521, or 1.2 percent, were undergoing self-care dialysis training.

Home Dialysis Population

There were 7,661 patients dialyzing at home at the end of 1980. This represents 14.6 percent of the total dialysis population.[1] The ESRD Networks' home dialysis populations range in size from 66 patients to 621 patients. Approximately two-thirds, 65.7 percent, of the home dialysis population are found in less than half (14) of the networks. The percentage of home dialysis patients in the Networks ranges from 5.2 percent to 45.1 percent. Of the home dialysis population, 4,715 or 62 percent, were using hemodialysis, 612 or 8 percent, were using peritoneal dialysis and 2,334 or 30 percent, were using continuous ambulatory peritoneal dialysis.

Continuous ambulatory peritoneal dialysis (CAPD) was not a reimbursable Medicare service until September 15, 1979. Prior to that time it was considered an experimental technique. CAPD involves filling the patient's peritoneal cavity with dialysis fluid and using the peritoneal membrane to filter waste products from the patient's blood into the dialysis fluid. The dialysis fluid is changed approximately 4 times per day, 7 days per week, through a permanently implanted catheter. CAPD requires the use of stringent sterile techniques but involves no dialysis machine and is by definition a home dialysis technique.

1/ As of June 30, 1981, there were 8,661 patients dialyzing at home out of a total dialysis population of 55,605. This represents 15.5 percent of the total dialysis populations. It is projected that as of June 30, 1982, 17 percent of the total dialysis population will be dialyzing at home.

NEW PATIENT CHARACTERISTICS

Total Dialysis Population

The total dialysis population increased by 6,970 patients. This is an increase of 15.4 percent. The ESRD Networks had total population growths ranging from 21 patients to 835 patients. On a percentage basis the range was 5.9 percent to 30 percent, with six networks reporting growth of over 20 percent.

In-Center Dialysis Population

The in-center dialysis population increased by 5,277 patients. This is an increase of 13.4 percent. However, the portion of the total dialysis population represented by in-center dialysis patients decreased from 86.9 percent in 1979 to 85.3 percent in 1980. The ESRD Networks had in-center population changes ranging from an increase of 6 patients to an increase of 706 patients.

Home Dialysis Population

The home dialysis population increased by 1,693 patients. This is an increase of 28.4 percent. The portion of the total dialysis population represented by home dialysis patients increased from 13.1 percent in 1979 to 14.6 percent in 1980. The ESRD Networks had home dialysis population changes ranging from a decrease of 8 patients to an increase of 130 patients. The portion of the total dialysis population represented by home dialysis patients within the individual Networks ranged from 5.2 percent to 45.1 percent. Compared to 1979, 8 Networks showed a decrease, 23 showed an increase and 1 remained unchanged in the percent of total dialysis population on home dialysis. The change in the percentage figures for the Networks ranged from -2.0 to +8.2, with 8 Networks reporting a change in their percentage of +2.0 or greater. Approximately 24 percent of the increase in the total dialysis population was comprised of home dialysis patients.

New Starts

Of the 19,687 patients starting a course of dialysis for the first time ever during 1980, 1,727, 8.8 percent, chose home dialysis and 17,960, 91.2 percent, chose in-center dialysis. An additional 620 received a transplant before ever starting a regular course of dialysis. Comparable figures for 1979 were 1,498, 8.4 percent, of the new starts choosing home dialysis, 16,243, 91.6 percent, choosing in-center dialysis, and 694 going directly to transplantation.

Changes in Treatment Setting

The data used to calculate the net increase in home dialysis patients for any given calendar year are year end figures. Therefore, every new patient choosing home dialysis may not be a home dialysis patient at the end of the year. Some of these patients receive a transplant, return to in-center dialysis, or die.

Analysis of the net increase in home dialysis patients shows that in 1980, 71 percent of the increase was due to shifts of patients from in-center dialysis to home dialysis, and the remaining 29 percent was due to new starts, restarts, or returns from transplant. This contrasts sharply to 1979 figures which showed 47 percent of the net increase in the home dialysis population due to shifts, and 52 percent due to new starts, restarts, or returns from transplant.

One possible explanation for the significant increase in shifts from in-center to home dialysis is CAPD. Further analysis reveals that the number of home patients choosing hemodialysis remained relatively constant, while the number of patients completing a CAPD training course was 2,293 in 1980. The overall growth in CAPD was 1,869 patients, from 465 in 1979 to 2,334 in 1980. CAPD offers many advantages to dialysis patients which could cause them to make this shift: for example, the absence of a machine, elimination of the need for a home aide, the short training period, freedom to travel, and less restrictive dietary routines.

Self-Care

Overall, patients performing some form of self-care comprises 17.1 percent of the total dialysis population. The distribution of patients in self-care is as follows:

TABLE 2. ANNUAL DISTRIBUTION OF SELF-CARE DIALYSIS PATIENTS

Treatment Setting	1979	1980
Home	5,968	7,661
In-center	620	781
Training	519	521
Percent of Total Dialysis Population	7,107 (15.7%)	8,963 (17.1%)

Although somewhat low, the 17.1 percent of patients in some form of self-care compares favorably with the 20-25 percent average rate of self-care in European countries such as France, West Germany, Sweden, and Switzerland.

Incidence

Two incidence figures have been calculated based on 1979 data. The first incidence figure is 71 per million for the Medicare-only population. This figure is calculated based on data from the entitlement tables, and includes only Medicare entitled patients, both new dialysis patients, and transplanted patients with no previous dialysis experience.

The second incidence figure of 78 per million is calculated based on the Facility Survey data for 1979. This figure is higher than the Medicare-only figure, probably because it includes all patients starting dialysis, not just those patients who have established Medicare entitlement by meeting the requirement of a three month waiting period. Some of the new starts may die before establishing Medicare entitlement. Studies have shown a much higher mortality rate during the first three months. For comparison purposes, the second incidence figure includes all new renal patients treated in Medicare approved facilities, all VA patients treated in Medicare approved VA facilities, only those transplanted patients with dialysis experience, and no VA patients treated in non-Medicare approved VA facilities

FACILITIES

As of December 1980, there were 1,068 hospitals and facilities approved to provide dialysis services. Of these, 534 were renal dialysis centers (RDC). An RDC is a hospital unit which provides the total range of diagnostic, therapeutic, and rehabilitative services, except transplantation, required for the care of ESRD dialysis patients. The remaining 534 facilities were renal dialysis facilities (RDF). An RDF is a facility, hospital based or independent, approved to furnish only dialysis services to ESRD patients.

The number of certified dialysis facilities increased in 1980 by approximately 10 percent (93). Ninety one percent (85) of these were RDF's and 9 percent (8) were RDC's. Each approved dialysis facility is certified to provide any of a variety of specialized services. These services include staff-assisted dialysis (extracorporeal or peritoneal), self-dialysis, home or self-dialysis training (extracorporeal and peritoneal dialysis) and CAPD training. Over 50 percent (579) of the approved facilities are certified to provide some type of home or self-dialysis training and about 10 percent (149) are approved to provide in-center self-care dialysis. Approximately 30 percent (320) of the total number of dialysis suppliers are for-profit organizations with approximately half of these chain-owned operations (see Figure 5.). The vast majority of the for-profit suppliers are free-standing RDF's.

As a condition of coverage, ESRD facilities (both RDC's and RDF's) are required to meet minimum utilization rates (MUR). Regulations specify the MUR's for which a facility will receive either an unconditional or conditional certification. However, regulations permit an exception to the MUR requirements for a facility that is determined not to have sufficient patients in its service area to meet such a rate, if the facility's absence would adversely affect the achievement of ESRD program objectives. The criteria for the MUR classifications are defined in 42 CFR 405.2100 (see Appendix C).

A total of 1,062 certified dialysis facilities have been classified by MUR. This number is six less than the total number of approved dialysis facilities. The unclassified six facilities are all RDCs which provide backup dialysis only, and thus do not have an MUR status.

The following numbers of facilities have been classified according to the MUR criteria established in regulation:

TABLE 3. MINIMUM UTILIZATION RATE STATUS

	Total	Unconditional	Conditional	Exception
Renal Dialysis Center	528	455	55	12
Renal Dialysis Facility (Hospital Based)	128	107	16	5
Renal Dialysis Facility (Independent)	406	336	68	2
Total	1062	898	139	19

The current MUR rates will be reviewed during FY 82. The assessment will evaluate the degree of correlation between the number of dialysis treatments and procedures performed, the quality of care patients receive, and the cost effectiveness of the treatments and procedures.

Other certification activities planned for FY 82 include:

1. Possible revision of need determination procedures to reduce the number of conflicting need recommendations received from the reviewing bodies and to centralize the need review in the State Certificate of Need agencies.

2. Inclusion of ESRD data in the Medicare-Medicaid Automated Certification System (MMACS) to provide automated information regarding deficiencies of ESRD providers and other related certification information.

3. Encouragement of self-dialysis programs through the development of training materials for facilities and patients.

4. Recodification of ESRD regulations

5. Evaluation of issues which may impact on the quality of care furnished by ESRD facilities.

Table 4

DIALYSIS TREATMENT SETTING OF ESRD PATIENTS BY ESRD NETWORK

ESRD Networks	Total Dialysis Patients	Dialyzed In-Center		Dialyzed At Home	
		Total	Percent	Total	Percent
1	374	308	82.3%	66	17.6%
2	1,376	755	54.8%	621	45.1%
3	2,258	2,009	88.9%	249	11.0%
4	4,080	3,831	93.8%	249	6.1%
5	885	616	69.6%	269	30.3%
6	871	744	85.4%	127	14.5%
7	750	553	73.7%	197	26.2%
8	603	455	75.4%	148	24.5%
9	1,338	1,016	75.9%	322	24.0%
10	788	638	80.9%	150	19.0%
11	3,615	3,193	88.3%	422	11.6%
12	1,102	1,026	93.1%	76	6.8%
13	620	470	75.8%	150	24.1%
14	1,834	1,504	82.0%	330	17.9%
15	2,600	2,466	94.8%	134	5.1%
16	1,046	594	56.7%	452	43.2%
17	968	822	84.9%	146	15.0%
18	2,594	2,104	81.1%	490	18.8%
19	2,813	2,601	92.4%	212	7.5%
20	2,285	2,051	89.7%	234	10.2%
21	1,277	922	72.2%	355	27.7%
22	2,139	1,877	87.7%	262	12.2%
23	1,060	937	88.3%	123	11.6%
24	2,434	2,134	87.6%	300	12.3%
25	3,920	3,505	89.4%	415	10.5%
26	1,018	857	84.1%	161	15.8%
27	727	648	89.1%	79	10.8%
28	1,954	1,728	88.4%	226	11.5%
29	711	640	90.0%	71	9.9%
30	1,607	1,326	82.5%	281	17.4%
31	643	563	87.5%	80	12.4%
32	2,074	1,810	87.2%	264	12.7%
TOTAL	52,364	44,703	85.3%	7,661	14.6%

Percentages may not add to 100.0% due to rounding.

Table 5

IN-CENTER SELF-CARE POPULATION BY TYPE OF DIALYSIS

	Hemodialysis		Peritoneal		Self-Care Training		
Network	Number	Percent	Number	Percent	Hemo	Peri	CAPD
1	118	38.3%	0	0.0%	9	0	0
2	4	0.5%	0	0.0%	15	3	6
3	93	4.6%	0	0.0%	13	0	14
4	63	1.6%	0	0.0%	38	1	0
5	31	5.0%	0	0.0%	6	0	0
6	7	0.9%	0	0.0%	0	0	4
7	0	0.0%	0	0.0%	0	0	1
8	0	0.0%	0	0.0%	7	0	2
9	0	0.0%	0	0.0%	15	0	2
10	0	0.0%	0	0.0%	1	0	0
11	57	1.8%	0	0.0%	16	3	11
12	4	0.4%	0	0.0%	2	2	1
13	29	6.2%	0	0.0%	7	1	2
14	18	1.2%	0	0.0%	14	1	6
15	63	2.6%	0	0.0%	21	0	4
16	0	0.0%	0	0.0%	25	1	3
17	31	3.8%	0	0.0%	6	0	3
18	9	0.4%	0	0.0%	12	2	4
19	62	2.4%	0	0.0%	1	0	2
20	22	1.1%	0	0.0%	11	1	3
21	0	0.0%	0	0.0%	11	0	1
22	18	1.0%	0	0.0%	11	1	0
23	3	0.3%	0	0.0%	15	1	7
24	16	0.7%	11	0.5%	12	9	2
25	21	0.6%	0	0.0%	23	4	5
26	8	0.9%	0	0.0%	19	6	12
27	12	1.9%	0	0.0%	2	0	4
28	10	0.6%	0	0.0%	10	2	0
29	0	0.0%	0	0.0%	1	0	1
30	15	1.1%	0	0.0%	7	2	3
31	24	4.3%	0	0.0%	4	1	2
32	32	1.8%	0	0.0%	36	4	1
TOTAL	770	1.7%	11	0.0%	370	45	106

Percentages may not add to 100.0% due to rounding.

Table 6

ANNUAL DISTRIBUTION OF HOME PATIENTS BY ESRD NETWORK

ESRD Network	1979 Home Patients Total	1979 Home Patients Percent	1980 Home Patients Total	1980 Home Patients Percent
1	69	19.5%	66	17.6%
2	492	45.1%	621	45.1%
3	186	9.3%	249	11.0%
4	158	4.3%	249	6.1%
5	231	30.4%	269	30.3%
6	74	10.6%	127	14.5%
7	173	25.6%	197	26.2%
8	116	22.6%	148	24.5%
9	251	21.8%	322	24.0%
10	131	18.0%	150	19.0%
11	293	10.5%	422	11.6%
12	54	5.7%	76	6.8%
13	111	19.3%	150	24.1%
14	214	13.0%	330	17.9%
15	107	4.8%	134	5.1%
16	401	43.3%	452	43.2%
17	121	14.3%	146	15.0%
18	395	17.8%	490	18.8%
19	149	6.2%	212	7.5%
20	204	11.0%	234	10.2%
21	266	25.7%	355	27.7%
22	207	10.7%	262	12.2%
23	32	3.4%	123	11.6%
24	242	10.7%	300	12.3%
25	285	8.4%	415	10.5%
26	169	17.8%	161	15.8%
27	35	5.3%	79	10.8%
28	169	9.2%	226	11.5%
29	49	8.3%	71	9.9%
30	267	19.0%	281	17.4%
31	78	14.2%	80	12.4%
32	239	13.5%	264	12.7%
TOTAL	5,968	13.1%	7,661	14.6%

Table 7

DESCENDING ARRAY OF 1980 PERCENT OF MEDICARE DIALYSIS POPULATION IN THE HOME BY ESRD NETWORK

Network	Percent of Medicare Dialysis Population in the Home: 1980	
2	45.1%	(45.1%)
16	43.2%	(43.3%)
5	30.4%	(30.4%)
21	27.8%	(25.7%)
7	26.3%	(25.6%)
8	24.5%	(22.6%)
13	24.2%	(19.3%)
9	24.1%	(21.8%)
10	19.0%	(18.0%)
18	18.9%	(17.8%)
14	18.0%	(13.0%)
1	17.6%	(19.5%)
30	17.5%	(19.0%)
26	15.8%	(17.8%)
17	15.1%	(14.3%)
6	14.6%	(10.6%)
32	12.7%	(13.5%)
31	12.4%	(14.2%)
24	12.3%	(10.7%)
22	12.2%	(10.7%)
11	11.7%	(10.5%)
23	11.6%	(3.4%)
28	11.6%	(9.2%)
3	11.0%	(9.3%)
27	10.9%	(5.3%)
25	10.6%	(8.4%)
20	10.2%	(11.0%)
29	10.0%	(8.3%)
19	7.5%	(6.2%)
12	6.9%	(5.7%)
4	6.1%	(4.3%)
15	5.2%	(4.8%)

Parenthetical figures represent comparative 1979 Network percent of Medicare dialysis population at home.

TABLE 8

RELATIVE RANKING OF NETWORKS
CHANGE IN PERCENT OF TOTAL DIALYSIS POPULATION ON HOME DIALYSIS
CHANGE FROM 1979 TO 1980

RANK	NETWORK	CHANGE IN PERCENT OF TOTAL DIALYSIS POPULATION ON HOME DIALYSIS
1	23	+8.2
2	27	+5.5
3	14	+4.9
4	13	+4.8
5	6	+3.9
6	28	+2.3
7	9	+2.2
8	25	+2.1
9	21	+2.0
10	8	+1.9
11	4	+1.8
12	3	+1.7
13	24	+1.6
14	29	+1.6
15	22	+1.5
16	19	+1.3
17	11	+1.1
18	12	+1.1
19	10	+1.0
20	18	+1.0
21	17	+0.7
22	7	+0.6
23	15	+0.3
24	2	0
25	5	-0.1
26	16	-0.1
27	20	-0.8
28	32	-0.8
29	30	-1.6
30	31	-1.8
31	1	-1.9
32	26	-2.0

Table 9

HOME PATIENT MODALITIES BY ESRD NETWORK

	Home Patients Hemodialysis		Home Patients Peritoneal Dialysis		Home Patients CAPD	
Network	Total	Percent	Total	Percent	Total	Percent
1	46	70%	0	0%	20	30%
2	482	78%	37	6%	102	16%
3	167	67%	5	2%	77	31%
4	108	43%	23	9%	118	47%
5	208	77%	23	9%	38	14%
6	59	46%	7	6%	61	48%
7	131	66%	21	11%	45	23%
8	71	48%	13	9%	64	43%
9	218	68%	15	5%	89	28%
10	97	65%	19	13%	34	23%
11	218	52%	48	11%	156	37%
12	33	43%	13	17%	30	39%
13	50	33%	16	11%	84	56%
14	159	48%	15	5%	156	47%
15	79	59%	6	4%	49	37%
16	350	77%	0	0%	102	23%
17	69	47%	8	5%	69	47%
18	359	73%	36	7%	95	19%
19	107	50%	6	3%	99	47%
20	122	52%	23	10%	89	38%
21	180	51%	55	15%	120	34%
22	149	57%	27	10%	86	33%
23	65	53%	0	0%	58	47%
24	142	47%	53	18%	105	35%
25	304	73%	5	1%	106	26%
26	122	76%	21	13%	18	11%
27	33	42%	0	0%	46	58%
28	177	78%	15	7%	34	15%
29	39	55%	0	0%	32	45%
30	162	58%	61	22%	58	21%
31	43	54%	22	27%	15	19%
32	166	63%	19	7%	79	30%
TOTAL	4,715	62%	612	8%	2,334	30%

Percentages may not add to 100.0% due to rounding.

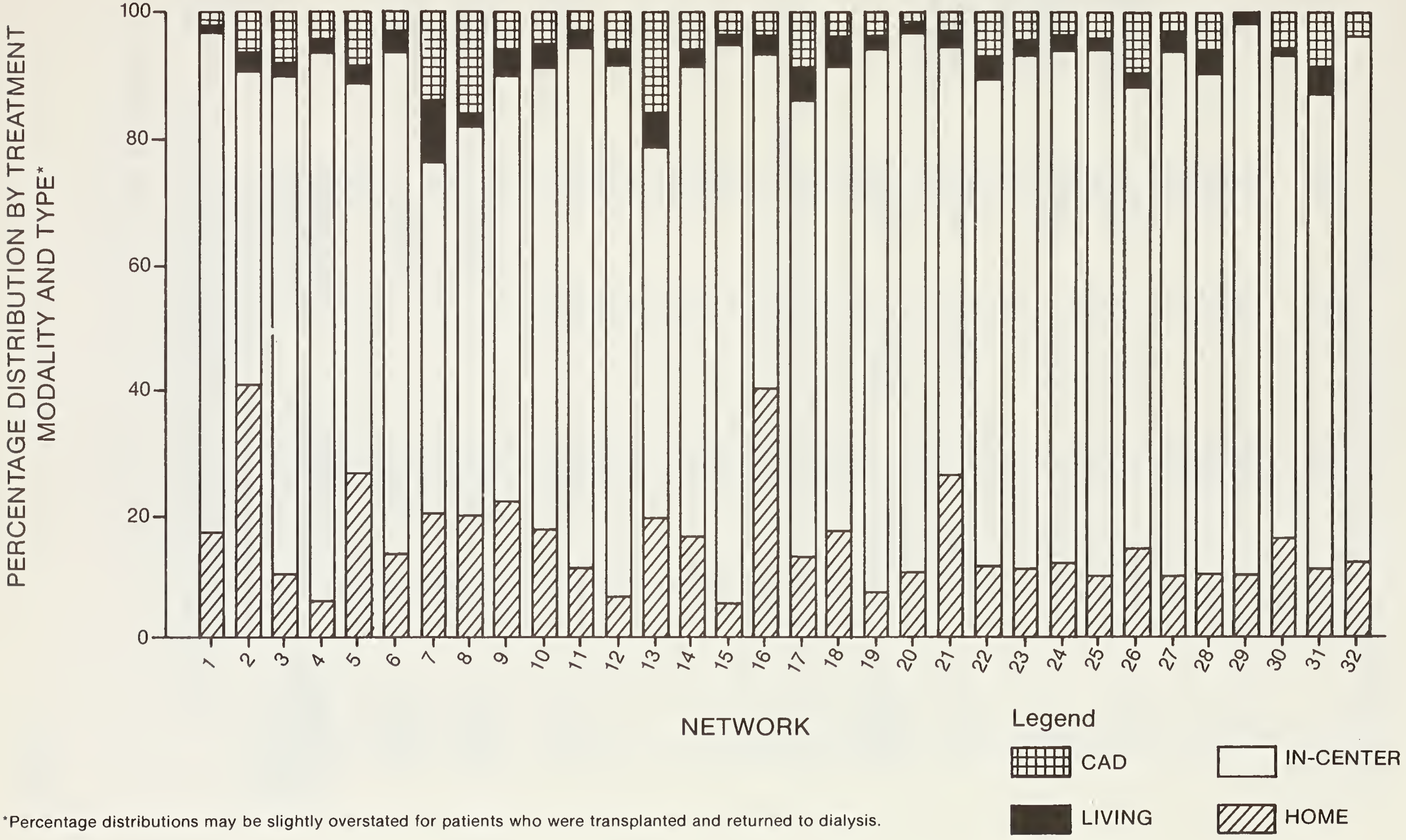
TABLE 10A CHANGE IN THE PERCENTAGE DISTRIBUTION OF THE DIALYSIS POPULATION, 1979 to 1980

	Total Dialysis Population	In-Center Dialysis Population	Home Dialysis Population
1979 Actual	45,393	39,426	5,968
Percent Distribution	100.00	86.86	13.14
1980 Actual	52,364	44,703	7,661
Percent Distribution	100.00	85.37	14.63
Change in Percent Distribution		-1.49	+1.49

TABLE 10B NUMBER AND PERCENT INCREASE OF DIALYSIS PATIENTS

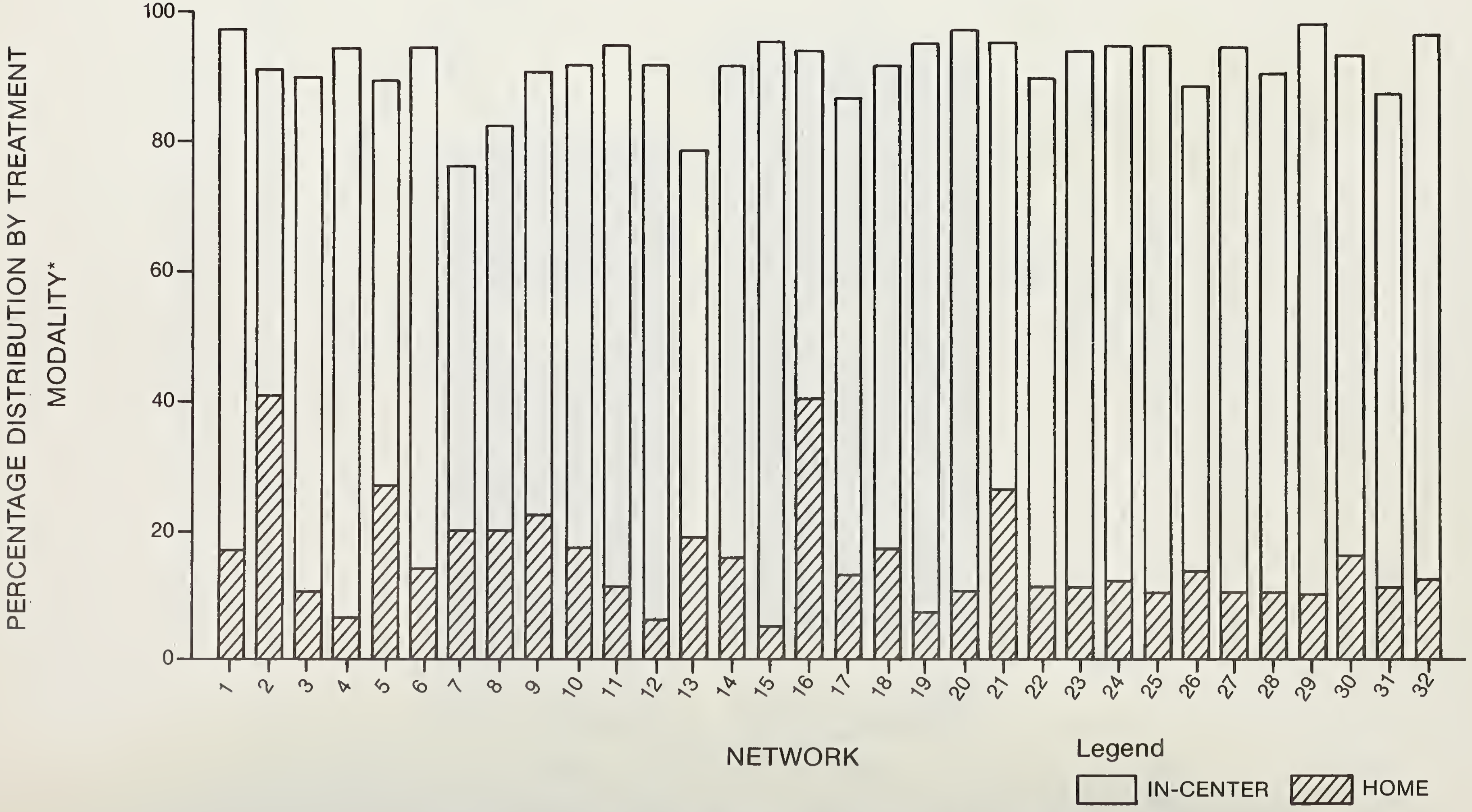
	1979	1980	Increase	Percent Increase
Total Dialysis Population	45,394	52,364	6,970	15.4
In-Center Dialysis Population	39,426	44,703	5,277	13.4
Home Dialysis Population	5,968	7,661	1,693	28.4

FIGURE 1. TREATMENT MODALITIES AND TYPES BY NETWORK



*Percentage distributions may be slightly overstated for patients who were transplanted and returned to dialysis.

FIGURE 2. TREATMENT MODALITIES BY NETWORK



*Percentage distributions may be slightly overstated for patients who were transplanted and returned to dialysis.

FIGURE 3. HOME DIALYSIS MODALITY — 1980

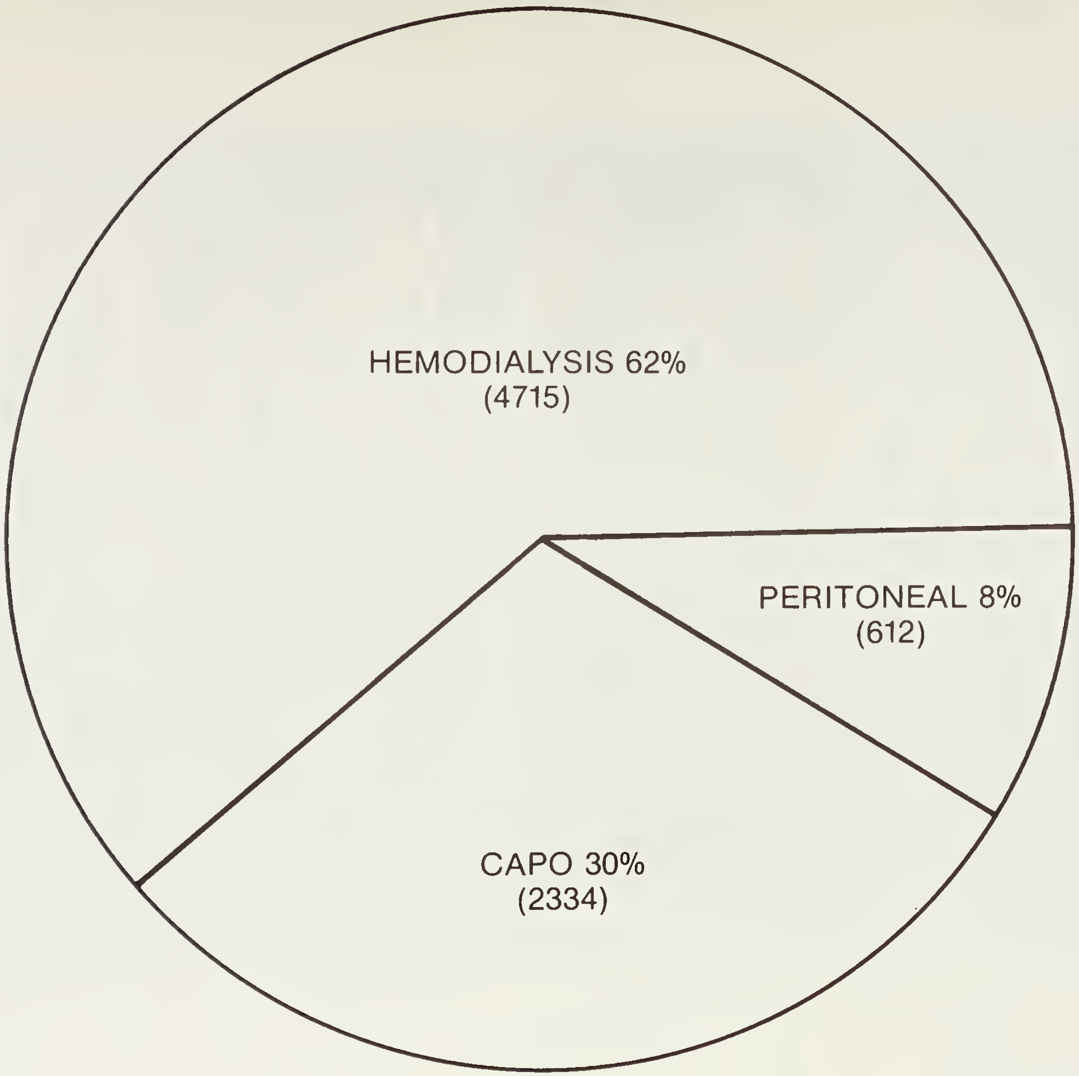


FIGURE 4. DIALYSIS SETTING 1979-1980

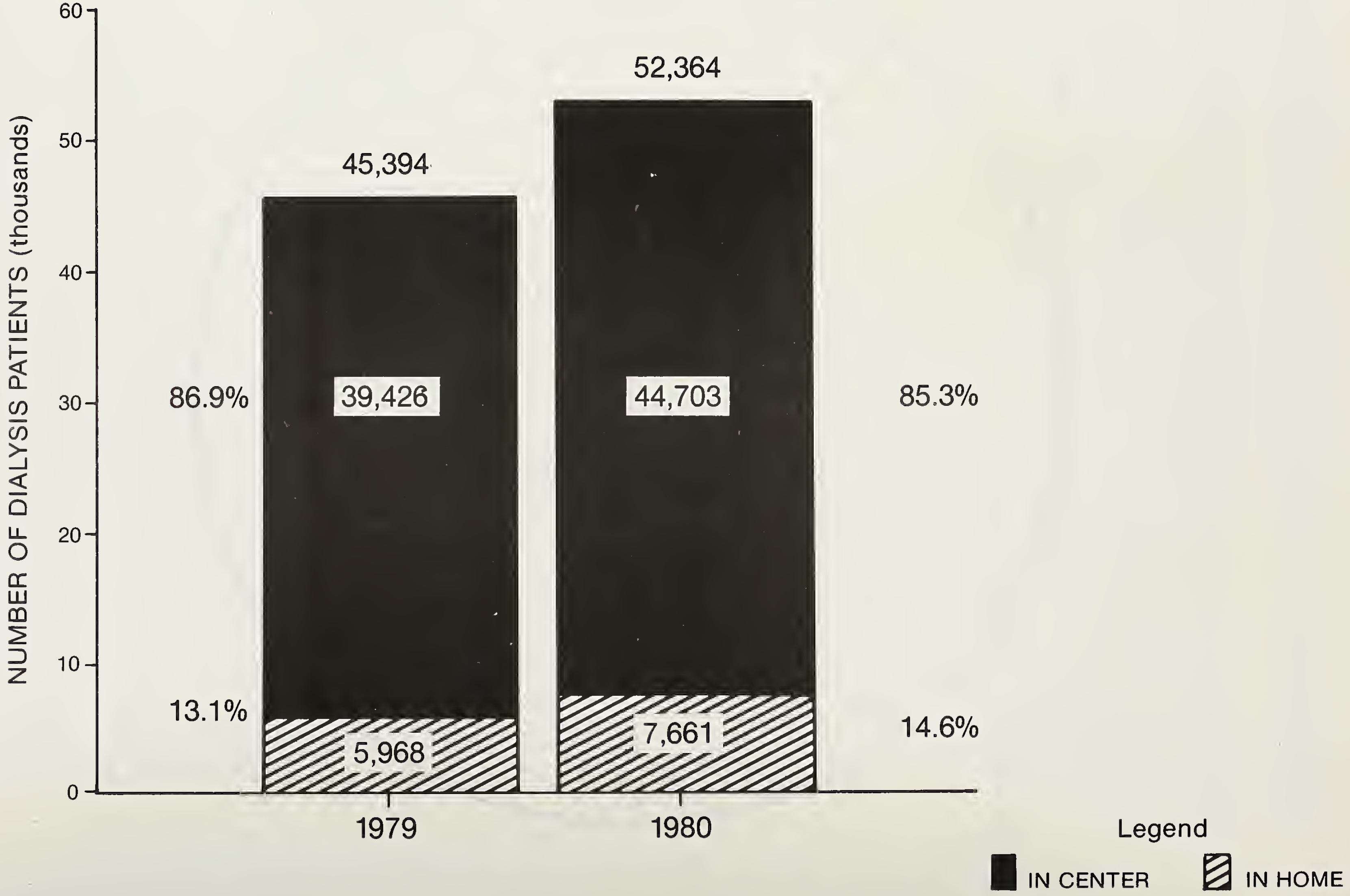
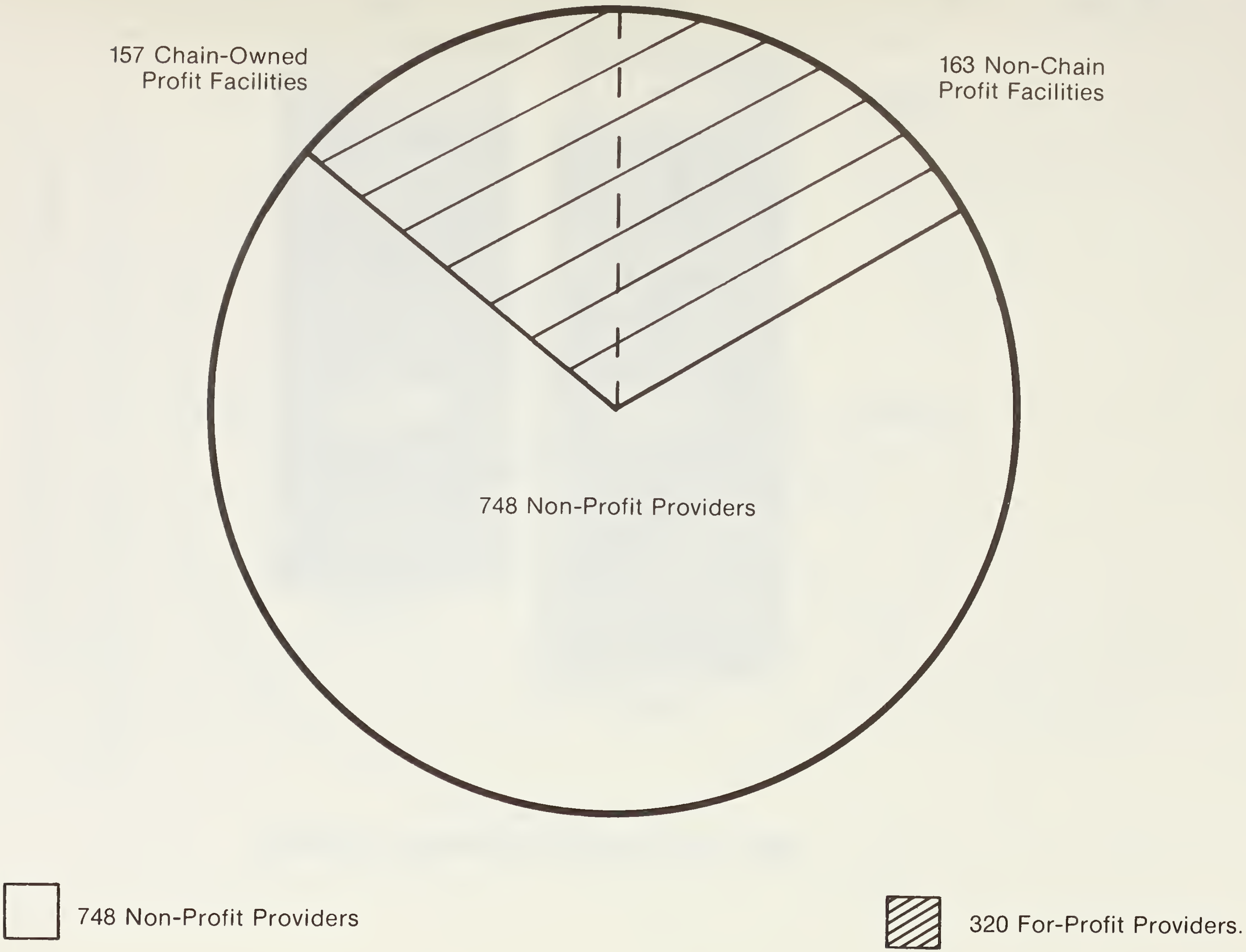


FIGURE 5. TYPE OF OWNERSHIP — PROFIT VS. NON-PROFIT 1068 ESRD PROVIDERS



TRANSPLANTS*

*Material in this section responds to:

Section 1881(g)(4) "the number of kidney transplants by source of donor organ"

Section 1881(g)(5) "the number of patients awaiting organs for transplant"

Section 1881(g)(6) "the number of transplant failures"

Section 1881(g)(7) "the range of costs of kidney acquisitions, by type of facility and by region"

Section 1881(g)(8) "the number of facilities providing transplants and the number of transplants performed per facility"

SUMMARY OF ACTIVITY

During 1980, 4,697 kidney transplants were performed. This represents an increase of 508 transplants, or 12.1 percent, over the 4,189 transplants performed in 1979. The increase was led by 5 Networks which increased transplantation by more than 50 percent. There were 12 Networks which reported decreases in transplantation, ranging from a 0.1 percent decrease to a 36 percent decrease. For the 20 Networks reporting increased activity, the increases ranged from 0.8 percent to 117.8 percent.

The absolute number of transplants involving living related donors (LRD) increased slightly, but the proportion of total transplants with living donors decreased. The percentage decrease is consistent with experience in other countries which have shown a continued trend toward heavier reliance on cadaveric donors for kidney transplants.

TABLE 11 ANNUAL DISTRIBUTION OF KIDNEY TRANSPLANTS, BY SOURCE OF DONOR ORGAN

Calendar Year	Total Transplants	Living Donor		Cadaveric Donor	
1979	4,189	1,186	28.3%	3,003	71.7%
1980	4,697	1,275	27.1%	3,422	72.9%

The number of LRD transplants in 1980 was 1,275, an increase of 89 (7.5 percent) such transplants over 1979. Cadaveric transplants, on the other hand, increased by 14 percent, with 419 more such transplants being performed in 1980 than in 1979. Eight Networks reported an increase in LRD transplants of more than 50 percent; three decreased such transplants by more than 40 percent; most Networks showed a modest change. Six Networks reported an increase in cadaveric donor transplants of over 50 percent; only two reported decreases of such transplants greater than 30 percent. Most Networks reported a modest change.

In 1980, 4,260 cadaveric kidneys were harvested and 3,422 or about 80 percent were transplanted. Even if each of the 838 unused kidneys had been suitable for transplant, it is clear that there would still be a shortfall of the number needed to transplant each patient on a registry. Not all kidneys are suitable for transplant. Several factors are critical to assure a successful match between a cadaveric kidney and a potential transplant recipient. One of the key factors is tissue typing. Many transplant surgeons require at least a 3 antigen match. A second key factor is timing. The cadaveric kidney must be speedily transplanted to assure a greater chance of success. Due to these and other factors, it is inevitable that some cadaveric kidneys will be wasted. This fact underscores the need to encourage expansion of organ procurement activities. In this regard, HCFA worked with the Public Health Service on a project to increase communications between kidney procurement teams and Emergency Medical Services hospitals. (See Tables 16, 17, and 18.)

PATIENTS AWAITING ORGANS

Patients may be on either formal or informal transplant registries, a fact which hampers efforts to identify the patients waiting for organs. However, the transplant hospitals report that they have a total of 4,825 dialysis patients on their transplant registries, a number almost unchanged from the 4,883 dialysis patients reported by transplant hospitals to be on transplant registries at the end of 1979. Dialysis facilities, on the other hand, reported that only 1,541 of their patients were on a transplant registry, down significantly from the 1979 figure of 6,410.

In last year's Annual Report the data indicated a perceptual difference between dialysis facilities and transplant hospitals. That is, dialysis facilities believed that many of their patients were on transplant registries, but transplant hospitals reported that a considerably smaller number were actually on active transplant registries. Possible explanations for this disparity were mentioned in last year's Report.

Subsequently, however, we were made aware of the possibility that the disparity was caused by a misunderstanding. Consequently, the instructions sent to each dialysis facility with the Facility Survey were changed to explicitly state that, in reporting patients awaiting organs, no individual was to be counted more than once. That is, even if an individual is on more than one transplant registry, that individual should only be counted once.

Using the revised instructions, transplant hospitals now report three times as many patients on transplant registries as the dialysis facilities. This may indicate that many patients are on more than one transplant registry, which is a desirable situation, since it enhances the chance of any one individual being matched with a suitable donor kidney. (See Table 19.)

TRANSPLANT FAILURES

Although exact information on the number of transplant failures is not available, information collected by HCFA shows that 1,398 patients returned to dialysis from transplantation during 1980. This figure represents 29 percent of all patients transplanted in 1980. Comparable figures for 1979 are 1379 patients, or 33.2 percent of all patients transplanted in 1979.

These figures appear consistent with data provided by The American Society of Transplant Surgeons as reported in the 1980 ESRD Annual Report to Congress. They reported a 20-25 percent failure rate for transplants involving a living related donor at 2 years, and a 30-43 percent failure rate at 2 years for cadaveric grafts.

However, it is important to note that these figures do not present a complete picture of transplant failures. For example, it is impossible to tell from these figures how many years a transplanted graft functioned before failing, since patients returning to dialysis from transplantation in 1980 may have received their transplant several years earlier. Further, data collected from ESRD facilities does not capture transplant failures which resulted in death.

KIDNEY ACQUISITION COSTS

Kidney acquisition services are those services necessary to identify potential donors, maintain a registry of patients awaiting transplant, ensure suitability and compatibility of the selected donor and recipient, excise the donor kidney, transport the organ to the transplant hospital, and maintain the viability of the organ until the time of transplantation. The charges for these services are accumulated and billed to the Medicare program by the hospital which performs the transplant.

The information available on kidney acquisitions is charge data rather than actual cost information. Charge data are received as individual bills and are recorded when the bills are submitted to the intermediary. Cost data are not available until final settlement of each hospital's audited cost report for the fiscal year in question.

For 1979, the overall national average kidney acquisition charge was calculated to be $5,906. For 1979 average kidney acquisition charges were not categorized by living related and cadaveric donor kidneys. During 1980 the national average kidney acquisition charge for a living related donor kidney was $7,581 and for cadaveric donor kidneys was $6,992. The range and average of kidney acquisition charges by DHHS Region are shown in Tables 13A and 13B.

To convert charge data to costs, we multiplied the charge by the applicable cost to charges ratio. For the sample of hospitals used to obtain kidney acquisition charge data, that ratio ranged from 54 percent to 100 percent. The calculations result in an average estimated national kidney acquisition cost for living related donor kidneys of $6,271 and for cadaveric donor kidneys the average estimated cost was $5,788. The range and average of estimated kidney acquisition costs by DHHS Region are shown in Tables 14A and 14 B.

The method of estimating kidney acquisition costs for 1980 differs from the method used in last year's report, which presented 1979 data. However, the data for 1979 showed an estimated overall national average kidney acquisition cost of $5,374.

Independent Organ Procurement Agencies

Some kidney acquisition services are performed for hospitals by independent organ procurement agencies (OPA). The services provided differ between OPAs, and range from providing only placement services, to providing all services except medical evaluation of the recipient or any living donors. The costs incurred by an OPA are billed to the transplant hospital and become a component of the hospital's kidney acquisition cost.

Independent OPAs are reimbursed on a cost basis. There are 21 operational OPAs which submitted cost reports during 1980. The cost per kidney for these OPAs ranged from $846 to $11,267. These figures are cost figures and as such are subject to adjustment on final cost settlement. The cost per kidney varies widely because of the variation in the number of kidney acquisition services performed by the individual OPAs. The data for OPAs was not broken down by type of kidney donor.

Table 15 shows the cost per kidney reported by the OPAs in each of the 10 DHHS Regions. One of the OPAs has been excluded from consideration because it is an umbrella organization, and its member OPAs are included in the data display. Only 1980 figures are shown because it was the first full year of cost reimbursement for independent OPAs.

FACILITIES

As of December 31, 1980, there were 151 hospitals approved by the ESRD program as transplant centers. Two of those transplant centers, both Veterans Administration hospitals, voluntarily discontinued their transplant programs, and were excluded from consideration. Thus, there are 149 approved transplant centers with active transplant programs.

Transplant centers are grouped according to the minimum utilization rate (MUR) certification standards. To achieve unconditional certification, a hospital must perform 15 or more transplants per year; for conditional certification, a hospital must perform 7-14 transplants per year; for exception certification, a hospital must perform less than seven transplants per year. One view is that transplantation success is more predictable at centers performing large numbers of procedures. Exception certification is granted only when requiring a higher level of performance would adversely affect ESRD program objectives, such as when a pediatric transplant center has low utilization. (See Table 20.)

The table below shows the range of the numbers of transplants performed, as reported by the hospitals, for 1980.

TABLE 12

RANGE OF THE NUMBERS OF TRANSPLANTS PERFORMED FOR 1980

Range of Number of Transplants Performed	Number of Centers	Percent	Accumulated Percent
0-6	9	6.0	6.0
7-14	27	18.1	24.2
15-24	42	28.2	52.3
25-49	47	31.5	83.9
50 or more	24	16.1	100.0

Similar data for 1979 showed 25.6 percent of the transplant centers performed 14 or fewer transplants. That figure has decreased to 24.2 percent in 1980. In 1979, 12.8 percent of transplant centers performed 50 or more transplants; for 1980 that figure had increased to 16.1 percent with 5 more transplant centers performing more than 50 transplants.

AVERAGE AND RANGE OF KIDNEY ACQUISITION CHARGES
LIVING RELATED DONOR KIDNEYS
FOR 1980, BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$ 5,700	$ 2,000	$4,366
New York	15,000	5,000	8,188
Philadelphia	11,675	1,957	7,216
Atlanta	10,139	3,871	6,612
Chicago	14,875	4,000	8,439
Dallas	14,000	4,000	6,586
Kansas City	14,240	7,000	10,468
Denver	5,746	5,000	5,373
San Francisco	11,000	5,500	7,948
Seattle	11,500	9,175	10,615
National	$15,000	$ 1,957	$7,581

Table 13B

AVERAGE AND RANGE OF KIDNEY ACQUISITION CHARGES
CADAVERIC DONOR KIDNEYS
FOR 1980, BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$10,000	$3,000	$5,937
New York	15,000	6,500	9,135
Philadelphia	10,922	1,957	6,480
Atlanta	8,670	3,000	6,484
Chicago	14,390	2,500	7,861
Dallas	9,000	4,263	5,980
Kansas City	19,250	7,000	10,838
Denver	5,445	2,400	3,923
San Francisco	7,500	5,250	6,221
Seattle	7,845	6,550	7,056
National	$19,250	$1,957	$6,992

Table 14A

AVERAGE AND RANGE OF ESTIMATED KIDNEY ACQUISITION COSTS LIVING RELATED DONOR KIDNEYS FOR 1980, BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$ 5,586	$1,790	$3,515
New York	10,719	3,573	5,851
Philadelphia	11,675	1,683	5,853
Atlanta	10,139	1,978	5,556
Chicago	13,536	3,491	7,732
Dallas	10,920	3,115	4,595
Kansas City	12,104	7,000	8,957
Denver	4,550	3,645	4,098
San Francisco	8,500	5,500	7,206
Seattle	10,228	8,243	9,354
National	$13,536	$1,683	$6,271

TABLE 14B

AVERAGE AND RANGE OF ESTIMATED KIDNEY ACQUISITION COSTS
CADAVERIC DONOR KIDNEYS
FOR 1980, BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$ 8,950	$2,100	$4,843
New York	10,719	4,645	6,528
Philadelphia	8,600	1,683	5,196
Atlanta	8,154	1,380	5,844
Chicago	13,095	2,343	7,267
Dallas	9,000	2,984	4,889
Kansas City	16,362	6,875	8,784
Denver	3,454	1,704	2,579
San Francisco	7,500	4,440	5,720
Seattle	7,048	5,695	6,226
National	$16,362	$1,380	$5,788

TABLE 15

Kidney Acquisition Costs Reported By Independent Organ Procurement Agencies By Region

REGION	COST PER KIDNEY
Boston	$ 5,731
New York	$ 846*
Philadelphia	$ 4,595 6,173 1,957*
Atlanta	$ 5,582 5,647 11,267 3,501
Chicago	$ 4,891 7,800 6,930
Dallas	$ 6,423 6,190 4,913
Kansas City	$ 8,954 6,802 5,263
Denver	No OPAs in this Region
San Francisco	$ 1,470*
Seattle	$ 7,301

*Limited Service OPAs

TABLE 16

DESCENDING ARRAY OF 1980 PERCENT OF TOTAL ESRD POPULATION TRANSPLANTED BY NETWORK

NETWORK	PERCENT OF TOTAL ESRD POPULATION TRANSPLANTED: 1980	
7	23.8	(26.1)
13	22.4	(23.2)
8	17.8	(16.9)
17	13.9	(14.7)
31	12.8	(14.8)
26	12.5	(10.0)
22	11.0	(10.8)
5	10.5	(7.9)
9	10.4	(11.3)
28	10.4	(9.1)
3	10.1	(10.0)
14	9.2	(10.2)
12	9.1	(5.9)
18	9.0	(5.1)
2	8.8	(11.4)
10	8.4	(9.5)
23	7.8	(7.8)
16	6.9	(8.6)
27	6.8	(6.8)
30	6.8	(8.0)
24	6.7	(6.7)
11	6.6	(8.3)
21	6.4	(10.1)
4	6.3	(5.7)
15	6.3	(6.2)
25	6.2	(7.2)
6	5.9	(11.0)
19	5.5	(3.9)
20	4.3	(5.5)
32	3.8	(4.2)
1	3.1	(4.9)
29	2.5	(1.8)

Parenthetical figures are values for 1979

TABLE 17

RELATIVE RANKING OF NETWORKS
CHANGE IN PERCENT OF TOTAL ESRD POPULATION TRANSPLANTED
CHANGE FROM 1979 TO 1980

RANK	NETWORK	CHANGE IN PERCENT OF TOTAL ESRD POPULATION TRANSPLANTED
1	18	+3.9
2	12	+3.2
3	5	+2.6
4	26	+2.5
5	19	+1.6
6	28	+1.3
7	8	+0.9
8	29	+0.7
9	4	+0.6
10	22	+0.2
11	3	+0.1
12	15	+0.1
13	23	0
14	24	0
15	27	0
16	32	-0.4
17	17	-0.8
18	9	-0.9
19	13	-0.9
20	14	-1.0
21	25	-1.0
22	10	-1.1
23	20	-1.2
24	30	-1.2
25	11	-1.7
26	16	-1.7
27	1	-1.8
28	31	-2.0
29	7	-2.3
30	2	-2.6
31	21	-3.7
32	6	-5.1

Table 18

ESRD NETWORK DISTRIBUTION OF KIDNEY TRANSPLANTS BY SOURCE OF DONOR KIDNEY TRANSPLANTS REPORTED IN CALENDAR 1980

Network	People	Transplants	Living Related		Cadaveric	
1	12	12	2	16.7%	10	83.3%
2	133	133	48	36.1%	85	63.9%
3	254	255	68	26.7%	187	73.3%
4	272	272	70	25.7%	202	74.3%
5	104	104	21	20.2%	83	79.8%
6	55	55	28	50.9%	27	49.1%
7	234	234	94	40.2%	140	59.8%
8	130	131	9	6.9%	122	93.1%
9	156	156	39	25.0%	117	75.0%
10	71	72	28	38.9%	44	61.1%
11	254	254	72	28.3%	182	71.7%
12	108	110	28	25.5%	82	74.5%
13	179	179	43	24.0%	136	76.0%
14	186	186	39	21.0%	147	79.0%
15	174	174	36	20.7%	138	79.3%
16	74	77	30	39.0%	47	61.0%
17	155	157	51	32.5%	106	67.5%
18	256	257	103	40.1%	154	59.9%
19	163	163	60	36.8%	103	63.2%
20	103	103	30	29.1%	73	70.9%
21	88	88	21	23.9%	67	76.1%
22	259	265	62	23.4%	203	76.6%
23	90	90	25	27.8%	65	72.2%
24	173	175	60	34.3%	115	65.7%
25	253	260	44	16.9%	216	83.1%
26	145	145	28	19.3%	117	80.7%
27	53	53	18	34.0%	35	66.0%
28	226	226	59	26.1%	167	73.9%
29	18	18	16	88.9%	2	11.1%
30	117	117	11	9.4%	106	90.6%
31	94	94	28	29.8%	66	70.2%
32	82	82	4	4.9%	78	95.1%
TOTAL	4,671	4,697	1,275	27.1%	3,422	72.9%

Percentages may not add to 100.0% due to rounding.

Table 19

ESRD NETWORK COMPARISON OF 1980 PATIENTS AWAITING TRANSPLANTS TO 1980 AND 1979 TRANSPLANTS

	Patients Awaiting Transplants				
ESRD Network	Dialysis Facility	Transplant Facility		1980 Transplants	1979 Transplants
		Dialysis	Non-Dialysis		
1	38	65	0	12	18
2	6	110	1	133	140
3	10	471	95	255	221
4	75	306	1	272	222
5	5	15	3	104	65
6	2	72	0	55	86
7	59	189	47	234	239
8	26	71	3	131	104
9	145	143	7	156	145
10	61	82	5	72	76
11	80	138	2	254	252
12	24	96	3	110	59
13	29	77	10	179	175
14	97	180	12	186	188
15	62	178	7	174	146
16	80	69	3	77	87
17	48	155	7	157	145
18	30	406	12	257	118
19	38	117	3	163	98
20	22	64	1	103	104
21	50	118	0	88	117
22	107	310	5	265	234
23	21	84	3	90	79
24	30	137	0	175	163
25	108	475	6	260	263
26	134	213	4	145	105
27	20	42	0	53	48
28	43	170	4	226	185
29	14	14	0	18	11
30	19	157	1	117	122
31	15	58	2	94	95
32	43	43	0	82	78
TOTAL	1,541	4,825	247	4,697	4,189

Table 20

ESRD NETWORK DISTRIBUTION OF TRANSPLANT CENTERS ARRAYED BY NUMBER OF TRANSPLANTS PERFORMED

Network	Transplants	0 Thru 6		7 Thru 14		15 Thru 24		25 Thru 49		50 Or More	
1	12	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
2	133	0	0.0%	1	25.0%	2	50.0%	0	0.0%	1	25.0%
3	255	0	0.0%	0	0.0%	0	0.0%	1	33.3%	2	66.7%
4	272	0	0.0%	4	36.4%	4	36.4%	2	18.2%	1	9.1%
5	104	0	0.0%	1	33.3%	0	0.0%	1	33.3%	1	33.3%
6	55	1	25.0%	1	25.0%	2	50.0%	0	0.0%	0	0.0%
7	234	0	0.0%	0	0.0%	0	0.0%	1	33.3%	2	66.7%
8	131	0	0.0%	0	0.0%	0	0,0%	1	50.0%	1	50.0%
9	156	1	12.5%	2	25.0%	2	25.0%	3	37.5%	0	0.0%
10	72	1	20.0%	1	20.0%	2	40.0%	1	20.0%	0	0.0%
11	254	0	0.0%	0	0.0%	2	33.3%	2	33.3%	2	33.3%
12	110	2	40.0%	1	20.0%	0	0.0%	1	20.0%	1	20.0%
13	179	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%
14	186	2	18.2%	4	36.4%	1	9.1%	4	36.4%	0	0.0%
15	174	0	0.0%	3	42.9%	2	28.6%	1	14.3%	1	14.3%
16	77	1	33.3%	0	0.0%	1	33.3%	1	33.3%	0	0.0%
17	157	0	0.0%	0	0.0%	3	50.0%	3	50.0%	0	0.0%
18	257	0	0.0%	1	25.0%	0	0.0%	1	25.0%	2	50.0%
19	163	0	0.0%	0	0.0%	1	25.0%	2	50.0%	1	25.0%
20	103	0	0.0%	2	50.0%	0	0.0%	1	25.0%	1	25.0%
21	88	0	0.0%	1	25.0%	2	50.0%	1	25.0%	0	0.0%
22	265	0	0.0%	0	0.0%	1	16.7%	3	50.0%	2	33.3%
23	90	1	20.0%	0	0.0%	3	60.0%	1	20.0%	0	0.0%
24	175	0	0.0%	1	20.0%	2	40.0%	1	20.0%	1	20.0%
25	260	0	0.0%	0	0.0%	3	50.0%	1	16.7%	2	33.3%
26	145	0	0.0%	1	20.0%	0	0.0%	4	80.0%	0	0.0%
27	53	0	0.0%	0	0.0%	1	50.0%	1	50.0%	0	0.0%
28	226	0	0.0%	2	22.2%	3	33.3%	3	33.3%	1	11.1%
29	18	0	0.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%
30	117	0	0.0%	0	0.0%	2	50.0%	2	50.0%	0	0.0%
31	94	0	0.0%	0	0.0%	1	33.3%	2	66.7%	0	0.0%
32	82	0	0.0%	0	0.0%	1	33.3%	2	66.7%	0	0.0%
TOTAL	4,697	9	6.0%	27	18.1%	42	28.2%	47	31.5%	24	16.1%
NATIONAL TOTAL			6.0%		24.2%		52.3%		83.9%		100.0%

Percentages may not add to 100.0% due to rounding.

FIGURE 6. TRANSPLANTS 1979-1980

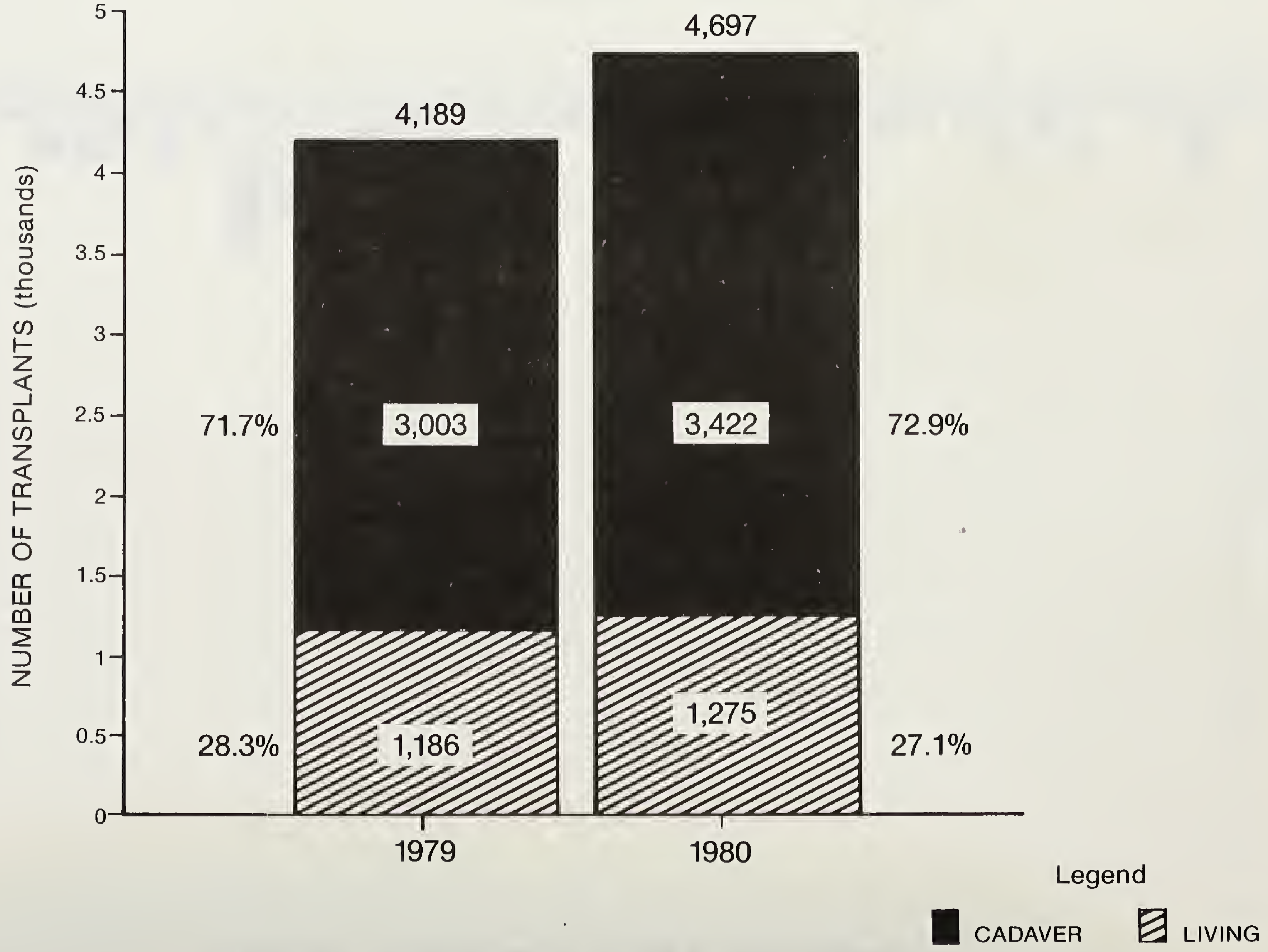
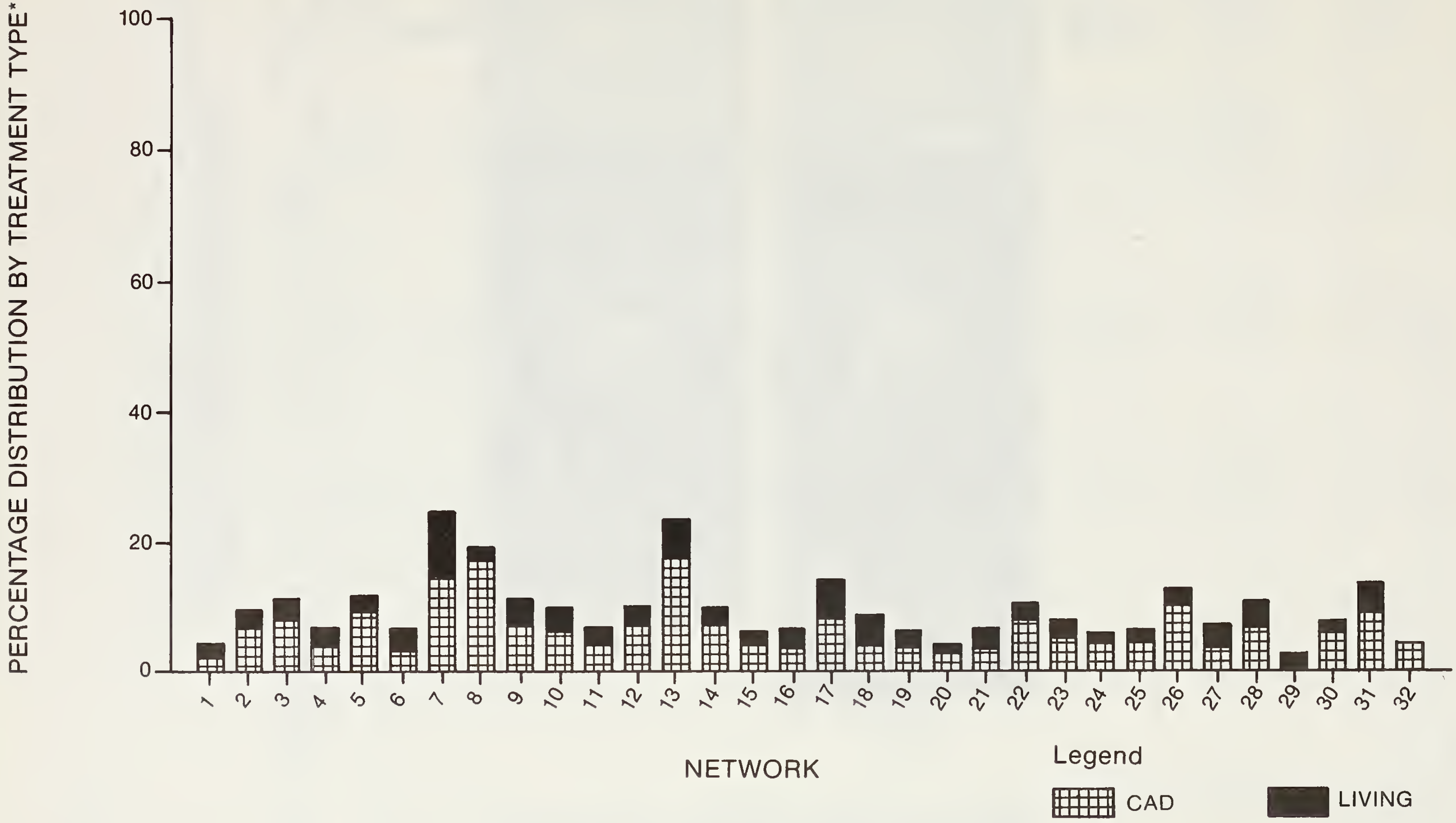


FIGURE 7. TREATMENT TYPES BY NETWORK



*Percentage distributions may be slightly overstated for patients who were transplanted and returned to dialysis.

MORTALITY AND MORBIDITY*

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*Material in this section responds to:

Section 1881(g)(9) "patient mortality and morbidity rates"

MORTALITY

The statistics furnished in last year's Annual Report represented our first effort at compiling mortality data for ESRD patients. As such, the data and analyses of that data were very basic. For this year's Report the data were significantly improved, allowing for more complete analyses. Thus, this year's statistics provide a greater depth of information about mortality among ESRD patients.

Methods

Several analyses were done in order to describe the mortality and survival experience of the End-Stage Renal Disease (ESRD) population. For simplicity, the analysis was restricted to those patients whose first treatment for ESRD (dialysis or transplant) occurred in August of 1973 or later. The analysis was further restricted to those for whom age, sex, and race were reported. Furthermore, since in the usual circumstance a patient did not become entitled for Medicare coverage until the date of renal transplantation or three months after the date of initial dialysis, whichever came first, the analyses were restricted to all transplant recipients and all dialysis patients who survived at least three months from first dialysis. A total of 61,737 ESRD patients met these inclusion criteria. In the first set of analyses this entire group comprises the study population.

For purposes of the calculation of the mortality rates and the modified life-table analyses, the date of entry for each patient was the date of first dialysis plus 90 days, or the date of first renal transplantation, whichever came first. The date of exit for these analyses was the date of death, the loss of part A entitlement, or March 31, 1980, which ever came first. The second set of analyses refers to individuals who were dialysis patients only and those who received at least three months of dialysis prior to a transplant. For these analyses, the date of entry is the date of first dialysis (August 1973 or later) plus 90 days and the date of exit is the date of first renal transplantation, date of death, loss of part A entitlement, or March 31, 1980, whichever came first.

The mortality analyses (Tables 21 and 23) were done in the standard manner for follow-up studies. In these analyses, the denominator for the age-specific rates was the accumulated number of years of life for each individual in the study population accrued between the entrance and exit dates for these analyses. These years for each individual are allocated to the appropriate age group for that person. The numbers of deaths were those occurring to the study population prior to the closing date for these analyses, allocated to the appropriate age-at-death category. The mortality rates were calculated by dividing the number of deaths by the appropriate number of accumulated person-years, and are expressed as mortality rates per 1,000 ESRD patients per year. Age-specific and total crude mortality rates are presented for the total study population and for the four race-sex groups which make up the population. In addition, an age-adjusted mortality rate is presented for the total and each race-sex group. The age-adjusted rate is the rate for each race-sex group adjusted by the direct method to the age distribution of the entire United States population in 1970. A total age, race, and sex adjusted rate is also presented for the entire study pouplation. This rate is the rate adjusted by the direct method to the age, race, and sex-specific distribution of the total U.S. population in 1970.

The survival analysis (Table 22) is a standard modified life-table analysis of survival and presents the number of patients who were alive at the beginning of each interval (each successive year following date of entry), the number of deaths occurring in the interval, the crude and relative survival rates for each particular interval, and the cumulative crude and relative survival rates for each successive interval. The relative survival rate adjusts for the "expected" mortality, based on the age, race, sex, and time-specific mortality, and the survival analyses were performed with the aid of a computer program specifically designed to perform such analyses on follow-up studies.

Results

Table 21 gives the age-specific and adjusted mortality rates for the entire ESRD population as defined above. Overall, the mortality rate in the period covered was 171 per 1,000 ESRD patients per year. The mortality rate rose progressively with age, and the age-adjusted rates tended to be slightly higher in men versus women (11-12 percent higher) and in whites versus nonwhites (2-4 percent higher). Table 22 presents the modified life table analysis for the total group and each of four race-sex specific groups. Overall, 23,193 deaths were observed in the study population. Survival was poorest within the first year after entry (relative survival= 83 percent). It should also be kept in mind that for the vast majority of the study population the first year of survival was also conditional upon having survived for three months from first ESRD treatment to entry into these analyses.

For each successive year-after-entry the survival in the interval progressively improved (improvements of 1 to 2 percent each successive year). This is so until the final category (the 7th year following entry). The relative survival in this period was 6 percent better than the survival in the 6th year. This apparent increase in survival in the 7th year may be due to an artifact of incomplete ascertainment of death, rather than any real improvement in relative survival for this period.

The data used to produce these analyses were those in the Medical Information System of the ESRD program as of September 1980. It was felt that due to the number of redundant mechanisms available for identifying mortality, that the ascertainment of deaths should be complete through March of 1980 on this file. Whether this improved survival in the 7th year post treatment is real or reflects incomplete ascertainment of deaths in 1980 should become clear with subsequent analyses. However, even if deaths within the first few months of 1980 were incompletely ascertained, because of the numbers involved in the various intervals, this should only materially affect the estimates of survival for the last interval. Because of this, the six year survival rates should be reasonably accurate. Overall the 6-year cumulative relative survival rate for this study population was 44 percent. This was similar between the race-sex groups, with the slight differences being in the same direction as those noted for the mortality rates. That is, females survived slightly better than males, and nonwhites slightly better than whites.

Table 23 gives the mortality analysis for the population of renal dialysis patients who were followed from 90 days post first dialysis treatment to transplant, death, or March 1980 whichever came first. Since the vast majority of the person-years accrued by the total study population was, in fact, accrued by dialysis patients, this analysis is quite similar to that presented for the total group.

Subsequent analyses will deal with patients having undergone renal transplantation, and will characterize their mortality and survival experiences for transplant patients as well as for those who returned to dialysis from transplantation. These analyses depend upon an evaluation of the data base in order to develop consistent and acceptable rules (given the manner in which the data were collected) for when a patient ceased to be a transplant patient and became a dialysis patient again. Such an evaluation process is currently underway and should allow for such analyses to be done in the next several months.

TABLE 21

Mortality rates (per 1,000 ESRD patients, per year) for entire study population whose date of first treatment was 8/73 or later, followed to death, termination of Part A entitlement or 3/80, by age, race, and sex, and adjusted* for these factors.

Age	White Male (53366)**	White Female (41796)	Non-White Male (21654)	Non-White Female (18855)	Total (135671)
20	53.8	58.1	61.6	60.8	57.0
20-24	73.2	65.5	76.9	67.1	70.6
25-29	82.4	93.3	80.7	84.3	85.6
30-34	111.9	105.2	94.3	103.5	105.7
35-39	125.3	118.5	107.5	88.4	115.0
40-44	142.6	107.1	111.0	106.1	120.7
45-49	158.5	122.7	143.6	114.2	138.1
50-54	169.9	137.8	168.8	141.0	154.6
55-59	205.3	170.7	181.9	163.8	183.7
60-64	231.7	193.6	236.3	186.5	213.3
65-69	295.2	262.5	283.5	264.6	279.4
70-74	380.2	301.7	309.8	308.9	337.9
75	475.7	453.0	458.6	322.8	450.6
Total	189.5	159.9	161.8	153.4	171.0
Age-Adjusted	130.1	117.7	124.6	110.9	119.9
Age, Race and Sex Adjusted					122.9

*Adjusted to the total U.S. population in 1970

**Total number of person-years included

TABLE 22

Modified life table analyses for all ESRD patients whose first treatment was 8/73 or after (Follow-up is to death or 3/80)

	Interval (yr)*	LX**	Deaths	Survival***	Survival****
TOTAL	0	61737	10564	0.82 (0.83)	0.82 (0.83)
	1	44641	6324	0.84 (0.85)	0.69 (0.71)
	2	27849	3290	0.86 (0.87)	0.59 (0.61)
	3	16616	1808	0.87 (0.88)	0.52 (0.54)
	4	9423	864	0.88 (0.89)	0.46 (0.48)
	5	4503	314	0.90 (0.90)	0.41 (0.44)
	6	1310	29	0.96 (0.96)	0.39 (0.42)
WHITE MALES	0	25123	4689	0.80 (0.82)	0.80 (0.82)
	1	17829	2770	0.82 (0.84)	0.66 (0.68)
	2	10902	1415	0.85 (0.86)	0.56 (0.59)
	3	6304	744	0.86 (0.87)	0.48 (0.51)
	4	3508	360	0.87 (0.88)	0.42 (0.45)
	5	1688	121	0.90 (0.90)	0.38 (0.41)
	6	522	16	0.94 (0.95)	0.35 (0.38)
WHITE FEMALES	0	18762	3097	0.83 (0.83)	0.83 (0.83)
	1	13704	1789	0.85 (0.86)	0.70 (0.71)
	2	8589	920	0.88 (0.88)	0.62 (0.63)
	3	5206	533	0.88 (0.88)	0.54 (0.55)
	4	2956	246	0.89 (0.90)	0.48 (0.50)
	5	1409	91	0.90 (0.91)	0.44 (0.45)
	6	405	6	0.97 (0.97)	0.42 (0.44)
NON-WHITE MALES	0	9560	1534	0.83 (0.85)	0.83 (0.85)
	1	7004	956	0.85 (0.86)	0.70 (0.73)
	2	4515	516	0.87 (0.88)	0.61 (0.64)
	3	2727	299	0.87 (0.88)	0.53 (0.56)
	4	1545	143	0.88 (0.89)	0.47 (0.50)
	5	729	53	0.89 (0.90)	0.42 (0.45)
	6	224	2	0.98 (0.99)	0.41 (0.45)
NON-WHITE FEMALES	0	8292	1244	0.84 (0.85)	0.84 (0.85)
	1	6104	809	0.85 (0.86)	0.71 (0.73)
	2	3843	439	0.87 (0.88)	0.62 (0.64)
	3	2379	232	0.88 (0.89)	0.55 (0.57)
	4	1414	115	0.90 (0.90)	0.49 (0.52)
	5	677	49	0.89 (0.90)	0.44 (0.46)
	6	159	5	0.94 (0.94)	0.41 (0.44)

*Interval from date of entry into analysis (Definition of date of entry given in methods.)
**Number of patients alive at the start of the specified interval
***Crude and relative survival rates for each interval. Relative survival rates given in parentheses.
****Cumulative crude and relative survival rates by interval from date of entry. Relative survival rates given in parentheses.

TABLE 23

Mortality rates (per 1,000 ESRD patients, per year) for the dialysis study population whose date of first reported dialysis was 8/73 or later, followed to transplant, death, termination of Part A entitlement or 3/80, by age, race and sex, and adjusted* for these factors.

Age	White Male (24,027)**	White Female (18,075)	Non-White Male (9,336)	Non-White Female (8,181)	Total (59,621)
20	51.0	51.0	53.7	61.6	52.3
20-24	76.3	74.6	75.4	71.4	84.5
25-29	90.9	100.4	81.3	88.1	91.5
30-34	117.9	104.8	92.6	97.9	106.6
35-39	125.1	117.5	104.9	87.4	113.4
40-44	147.0	105.5	110.2	99.6	119.9
45-49	154.8	123.3	139.8	112.4	135.9
50-54	164.9	136.1	169.9	136.9	151.6
55-59	204.8	171.6	181.0	165.3	184.1
60-64	231.7	194.1	235.3	185.7	213.1
65-69	296.1	262.7	283.4	264.6	279.7
70-74	380.2	301.7	310.8	308.9	338.1
75+	476.3	453.0	462.9	322.8	451.2
Total	210.2	167.7	165.8	155.6	
Age-Adjusted	130.0	116.1	121.2	110.8	

Age, Race and Sex Adjusted = 121.9

*Adjusted to the total U.S. population in 1970

**Total number of person-years included

In 1980, ESRD facilities reported 10,213 deaths of ESRD patients. Home dialysis patients accounted for 1,038 of this total. Comparable figures for 1979 were 8,440 deaths, of which 643 were home patients.

For purposes of analysis, a crude mortality rate by treatment setting was calculated by dividing the total number of deaths by the total average enrollment during the calendar year, assuming equal rates of entry, exit, and shifts between treatment modalities during the year. The results are as follows:

Treatment Setting	1979	1980	Percent Change
Home	11.9%	15.1%	+3.2%
In-Center	21.2%	21.6%	+ .4%
Total	20.0%	20.7%	+ .7%

The overall mortality rate increased only slightly, by .7 percent. The mortality rate for in-center patients remained higher than that for home patients, although the gap between the two rates decreased as the mortality rate for home patients increased by 3.2 percent compared to an increase of only .4 percent for in-center patients. One possible explanation for this increse might be the increasing number of diabetics shifting from in-center treatment to treatment by continuous ambulatory peritoneal dialysis. This population, on the average, experiences a higher mortality than the non-diabetic ESRD population. HCFA plans to study this area in depth, and will report on its findings when available.

INPATIENT UTILIZATION

The number of inpatient hospital admissions, and the days of inpatient care utilized, can be used as an indicator of the relative success of medical management of patients with end-stage renal disease. Since the data include admissions for all reasons, they are not true indicators of morbidity, but only a rough measure of overall health.

The data was gathered from hospital bills posted as of February 20, 1981. Excluded from the tables are data on individuals who were still patients as of January 1, 1981. That is, the tables reflect data only from patients whose inpatient stay ended on or before December 31, 1980.

The following tables show the number of patients requiring hospitalization and the number of admissions required by those patients.

TABLE 24 PATIENTS BY NUMBER OF ADMISSIONS

1979

Admissions	Patients	Distribution
1	15,485	43.3%
2	8,741	24.4%
3	5,209	14.5%
4	2,894	8.1%
5+	3,461	9.7%

Total Patients - 35,790

1980

Admissions	Patients	Distribution
1	16,851	45.0%
2	9,423	25.2%
3	5,289	14.1%
4	2,913	7.8%
5+	2,981	7.9%

Total Patients - 37,457

The number of patients requiring hospitalization increased 4.7 percent from 1979 to 1980. The increase in patients hospitalized was distributed primarily within the group of patients requiring three or fewer admissions although the number of patients requiring four admissions increased by 0.3 percent. In 1979, 17.8 percent of the patients required four or more admissions, while in 1980 only 15.7 percent of the patients required four or more admissions.

The following table shows the total days of inpatient care, for renal and non-renal conditions, utilized by ESRD patients and the average length of stay.

TABLE 25 INPATIENT DAYS OF CARE UTILIZED

	Patients Discharged		Patients Deceased	
	Total Days of Care	Average Length of Stay	Total Days of Care	Average Length of Stay
1979	858,610	11	79,892	21
1980	792,872	10	69,687	19

Thus, the data show that during 1980 the rate of admission to a hospital declined relative to the increase in the ESRD population and that the average length of stay during an admission also declined. One possible conclusion that can be drawn from the data is that there is improved health in the ESRD population and an improved ability of the medical community to maintain an ESRD patient in a stable state.

COSTS*

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*Material in this section responds to:

Section 1881(g)(10) "the average annual cost of hospitalization for ancillary problems in dialysis and transplant patients, and drug costs for transplant patients"

Section 1881(g)(11) "Medicare payment rates for dialysis, transplant procedures and physician services along with any changes in such rates during the year and reasons for those changes"

Section 1881(g)(12) "the results of cost savings experiments"

HOSPITALIZATION FOR ANCILLARY PROBLEMS

In the case of transplant patients, we have defined ancillary problems as those stemming from causes other than hospitalization for the actual transplant. For dialysis patients, we assume that their dialysis treatments are maintenance treatments, that is, they are required about three times a week and can be done on an outpatient basis. Therefore, we have assumed that any hospitalization of a dialysis patient will be for an ancillary problem.

To compute the expenditures for these ancillary problems, we reviewed a four-month sample of Medicare ESRD patients' inpatient bills. The total charges for any hospitalization during which a transplant was performed were excluded, as well as any charges for dialysis treatments while the patient was hospitalized. The result represents reasonable data on charges for services provided to transplant and dialysis patients for treatment other than the transplant and dialysis.

The data available on hospitalization for ancillary problems are charges rather than actual cost information. Charge data are received as individual bills and enter the system when the bills are submitted. Cost data are not available until final settlement of each hospital's audited cost report for the fiscal year in question.

In order to approximate the cost of providing inpatient care for ancillary problems, the charges for hospitalization for ancillary problems were multiplied by the overall Medicare cost to charges ratio. The results of these calculations are shown below and depict the charge and estimated cost per admission, for treatment of ancillary problems in dialysis and transplant patients.

Average Charge For Hospitalization For Ancillary Problems	Estimated Cost of Hospitalization For Ancillary Problems
$4,169	$2,979

DRUG COSTS FOR TRANSPLANT PATIENTS

Under the Medicare program, drug costs are covered for in-hospital patients, whereas for ambulatory patients they are not. Since only a small proportion of Medicare beneficiaries have private health insurance that covers drugs, it is generally felt that the costs might be significant if borne out of pocket by the beneficiary.

A study was conducted to estimate the monthly costs of drugs for ambulatory kidney transplant patients. As will be shown below, the study indicated that drug expenditures for transplant patients were considerable, with an average from the three centers responding to the survey ranging from in excess of $45 to over $103 per person per month. There was a wide range in the monthly costs per patient, and the costs of antihypertensive drugs in particular appear to be a significant contributing factor in the variability of these costs, amounting in two centers to averages of $28.01 and $33.59 per user per month.

In order to obtain estimates of these costs, HCFA asked the American Society of Transplant Surgeons to furnish typical drug regimens for ambulatory transplant patients, in the form of averages and ranges of dosages; we also asked for unit drug cost information. Based on prior discussions with knowledgeable professionals, our request indicated the assumptions HCFA chose to make: the use and costs of the drugs should be estimated without regard for whether third-party coverage existed for them, and the drugs should include over-the-counter as well as prescription drugs, since antacids and vitamins had been cited as significant cost items. We asked for this information by the four major categories of drugs that these professionals had indicated were specifically related to transplantation, plus a fifth category, antihypertensives, that they felt represented a considerable potential among transplant patients for beneficiary cost burden. The five categories were:

- immunosuppressives
- steroids
- antacids
- vitamins
- antihypertensives

In response to this request, the Society provided tabular data from three transplant centers, each located in a different area of the county. In this regard, it should be noted at the outset that these data do not constitute a representative sample of transplant centers or patients since the sample is of limited scope and validity. For the purposes of this report, the centers are identified as "A, "B" and "C," and summary information and discussions are provided for each.

In the tables presented for each center, statistics on the costs of steroids are combined with those for immunosuppressives, since they are used for related purposes in 100 percent of transplant patients, and antacids (where reported) and vitamins are combined under the "supplemental" category. In addition, statistics on the costs of diuretics are combined with those for antihypertensive drugs, since they also are used for a medically related purpose and since 85 to 90 percent of patients on antihypertensive drugs use both categories.

The following presents a summary for each center.

Transplant Center A

Center A, which is located in the northeastern United States, provided detailed prescription information on 48 of approximately 100 patients being followed there, together with average costs per specified dosage for each of the drugs identified. (It should be noted that having detailed information on each patient permits far greater accuracy in compiling averages and ranges in costs among patients using more than one drug in each category.) The first two rows in Table 26A display the average monthly costs and the ranges in monthly costs for the users of drugs in each of four major categories, and the third row gives the percent of patients using any drugs in the respective category. Restricting these rows to users gives a more realistic picture of what these cost burdens can be for individual patients, and the percentages give an indication of the breadth of patient use in that category. The fourth row in the table presents the average costs in each category for all patients, including nonusers, to provide a better estimate of costs across all transplant patients. The average and range of total costs in Table 26A is for all 48 patients.

Overall, the average monthly drug cost from Center A is $49.12 per person. Of particular note in Table 26A is the wide range of monthly estimated drug costs for all patients, and especially the range of such costs for antihypertensive (including diuretic) drugs. Not reflected in Table 26A is the fact that three of the 48 patients from Center A had total estimated monthly costs in excess of $100, and six more had between $70 and $100 per month in estimated costs. It appears that antihypertensive drugs costs contribute significantly to this variation since the range for this category alone was from $73.83 to $146.03 per person per month for the three patients with total monthly costs over $100, and from $41.47 to $77.83 for the six patients whose total drug costs were between $70 and $100 per month.

Apparently not reported in the data furnished by Center A was information regarding antacids. If the cost estimates for this category from the other two centers (see below) are valid for these patients as well, the total monthly costs of drugs could be increased by over $20 per person.

Transplant Center B

Center B, which is located in the southern United States, provided detailed individual drug data on 10 patients; Table 26B displays aggregate statistics from this data.

This table displays two differences from Table 26A that merit explanation. First, the average monthly costs for immunosuppressives are much higher than those from Center A, at $58.89 per month with a range of $49.69 to $66.15. By and large, this derives from unit drug costs quoted by Center B that were over twice that quoted by Center A. This illustrates that variations among locations or centers in drug costs and dosages, and possibly the mix of patient illness and need, can greatly affect drug costs for transplant patients. For antihypertensives on the other hand, the differences beween Centers A and B for monthly costs (and quoted unit drug costs, not shown) were not so large. Second, the "supplements" column also displays higher costs figures, which can be accounted for almost entirely by the cost of antacids, not reported by Center A. The total monthly drug costs for individual transplant patients at Center B ranged from $74.70 to $145.95, and averaged $103.47. The average monthly cost for immunosuppressives, steroids and supplements was $81 per person, with a range of $68.85 to $103.35; for antihypertensive and diuretic drugs the average for users was $28.01 per person per month, with a range of $10.80 to $77.10 per person for the 80 percent of the Center B patients using this category of drugs. As noted above, the higher average for total drug costs reports by Center B compared with Center A appears to be due primarily to the higher unit costs quoted for the immunosuppressives and the inclusion of antacids.

Transplant Center C

Center C, located in the western United States, provided monthly aggregate estimates for three principal drugs for ambulatory transplant patients, and Table 26C displays the most pertinent of these: the estimated monthly cost for immunosuppressives (including steroids) is $21.84, which corresponds closely with the $23.27 for the same category from Center A, but is considerably below that from Center B. Center C also gave $24.37 as an estimated monthly inpatient cost for antacids and that amount is also shown in Table 26C. It should be noted that it also corresponds very closely with the $22.17 average in the same category from Center B also made up almost entirely of antacids.

The combined monthly costs estimated by Center C for immunosuppressives, antacids and other supplements is $46.21. If approximations of the very similar costs for antacids reported by Centers B and C is added to Center A's $23.27, the resulting $46 to $48 per person would correspond closely indeed to the $46.21 from Center C.

Total monthly estimates for all categories of drugs from Center C could not be calculated because of insufficient data on the other drugs.

Conclusions

This limited survey cannot be interpreted to show transplant patient drug cost experience around the country. Nevertheless, for these three centers, the average monthly costs for the drug categories studied ranged from over $45 to over $103 per person. Perhaps of greater significance is the fact that average costs alone may not reflect the potential burden on many beneficiaries, since the range in costs, notably antihypertensives in this survey, can be dramatic.

In the future, HCFA intends to carry out a wider survey of transplant centers with the view of obtaining more uniform and more representative data. In the meantime, the results of this survey can give some indication of the nature and scope of the drug cost burden for this group of beneficiaries.

DIALYSIS PAYMENT RATES

The average payment rate for maintenance dialysis in 1980 was $148 per treatment. This payment rate reflects the combined weighted average of the payment to each of the two types of ESRD facilities: hospital-based and non-hospital (freestanding). Hospital-based facilities are paid the lesser of their cost or a national payment screen. Their average reported cost/payment in 1980 was approximately $158 per treatment (exclusive of physicians services). Freestanding facilities are paid the lesser of their charge or a national payment screen. Their average payment exclusive of physicians services was $138 per treatment.

TRANSPLANT PROCEDURES

To compute the expenditures for transplant procedures, we reviewed a four-month sample of bills submitted to the Medicare program by transplant hospitals. We determined that, for 1980, the average charge for the transplant procedures, including the charge for the donated kidney, hospitalization, and other ancillary services, was $20,156.

The data available represents charges, not actual costs. Charge data are received as individual bills and are entered in the system when the bill is submitted. Cost data are not available until final settlement of each hospital's audited cost report for the fiscal year in question.

In order to approximate the cost of transplant procedures, the average charge for transplant procedures was multiplied by the overall Medicare cost to charges ratio, resulting in an estimated cost for transplant procedures of $14,403. For 1979, a different cost to charges ratio was used and the average charge for transplant procedures was $19,300, resulting in an estimated cost of $17,563.

PHYSICIAN SERVICES

The payment rates for physician services can be categorized by the type of treatment the patient receives, either dialysis or transplant.

Dialysis

Dialysis physicians are reimbursed under one of two methods--the initial method and the alternative method. Under the initial method, physicians receive payment for their supervisory dialysis services directly from the facility, usually under a salary or contract arrangement. Other services required by the patient (not considered routine) are billed to the Medicare program by the physician on a fee-for-service basis.

Under the initial method, the average payment rate to physicians for supervisory services during dialysis is part of the overall dialysis charge billed by the facility. Since provider facilities (i.e., hospitals) are paid on a cost basis, the physician component of the total cost is identifiable. Based on unaudited cost reports submitted by provider facilities, the average payment for physicians' supervisory dialysis services is $13 per treatment.

Under the alternative reimbursement method, physicians are paid a monthly fee for each patient for all renal care of that patient. This includes supervisory services during dialysis, plus all other renal related services, complicated or routine, furnished during a particular month.

The alternative monthly allowances for physician services to patients dialyzing in a facility ranged from a minimum level of $180 to a maximum level of $260. The allowances for physician services for treatment of patients dialyzing in the home ranged from a minimum level of $126 to a maximum level of $182. The lower payment rates for home dialysis are due to the fewer services rendered to home dialysis patients.

Physician payments are subject to the Supplementary Medical Insurance (Part B) coinsurance and, thus, Medicare reimbursement is made for 80 percent of the allowed charge.

Transplant

Transplant physicians perform two types of services--the excision of the donated kidney, and the implantation of the kidney. The excising surgeon's payment rate is $350 for one kidney excised and $700 for two. These charge allowances have been in effect since the inception of the ESRD program.

For the transplant of the kidney, the average payment depends on the extent of other services provided by the physician, i.e., if a splenectomy procedure is included when the transplant is performed, or whether immunosuppressive therapy is provided after the transplant. The allowed charges for the transplant and other services ranged from $1,827 to $2,250.

CHANGES IN DIALYSIS RATES

Any ESRD facility desiring a payment rate above the national payment limit must request a reimbursement exception and submit documentation of its higher costs. During 1980, 414 requests for reimbursement exceptions were received. That is an increase of 113 over the number of exception requests received during 1979.

During 1980, a total of 262 exception requests were approved (in full or in part), 73 were denied on the basis that the request was not sufficiently justified, and 78 were denied on procedural grounds, most commonly because the necessary forms were not properly completed. Some of the requests considered during 1980 were actually received during 1979.

Approval of a rate change depends on the characteristics of the individual facility. Presently, some of the more prevalent reasons for approval include the following (but may change as a result of new incentive reimbursement regulations):

1. Treatment of a more seriously ill population;
2. Treatment of an unusual patient population (e.g., children);
3. Location in a high cost or low utilization area;
4. Low utilization due to sporadic workload (a hospital treating cases only as referred).

The ranges of payment rates requested is depicted in Table 27A. The range of payment rates approved in excess of program payment screens is depicted in Table 27B.

COST SAVINGS AND OTHER ESRD EXPERIMENTS

Home Dialysis Aide Experiments

The Health Care Financing Administration is sponsoring three demonstration projects which change ESRD benefits by extending coverage to the services of a dialysis aide for maintenance dialysis sessions performed in patients' homes. The primary purpose of all three demonstration projects is to test whether providing this extra benefit results in more patients choosing home dialysis as a treatment option, and to determine the impact on quality of care.

There are two categories of paid aides covered under the demonstration. The first, known as "partners," are family or household members. The second, known as "assistants," are non-family or non-household members who can qualify to perform this service.

All paid aides, both partners and assistants, receive training from an approved program in a participating dialysis facility. After satisfactorily completing the training course, aides are certified by their respective facilities to assist the patient with whom the aide was trained. "Assistants" are directly employed by the training facility, the patient, or an independent agency, depending on the model followed at the individual demonstration sites. All patients and aides receive ongoing direction and supervision from the participating dialysis facilities.

Both "partners" and "assistants" receive payment for their services; "partners" receive a monthly payment equal to approximately one-half the amount that assistants receive. In addition, under the demonstration, transportation costs of aides are a covered service, as well as increased support and monitoring services.

The three contractors which were chosen to design and implement these demonstration projects were System Sciences, Inc., Research Triangle Institute, and the University of Utah. The System Sciences demonstration began on April 1, 1978. It involves the participation of eight experimental facilities located in six different states: New York, Massachusetts, Mississippi, Florida, Minnesota and California. The Research Triangle Institute demonstration began on October 1, 1978; it involves the participation of 10 dialysis facilities located in North Carolina. The University of Utah demonstration began July 1, 1978; it involves the participation of eight experimental facilities located in Utah and Colorado.

Each project involves three separate phases of operation. Phase I was the design phase; Phase II was the 3-year patient intake phase; and Phase III is a 6-year period in which benefits will be extended to patients enrolled during Phase II and the evaluation of the experiments will be completed.

All three projects are now in their third and final year of the operational phase of the demonstration (Phase II). Prior to these demonstrations, there was a decreasing trend in the proportion of patients using home dialysis. Results thus far show increases at the experimental sites in the percentage of patients choosing home dialysis. In the System Sciences project, over a 2-year period, the percentage of home patients in experimental facilities increased from 26 to 34 percent whereas home dialysis patients in the control facility decreased from 26 to 23 percent. Of all new patients in the experimental facilities, 51 percent chose home dialysis compared to only 12 percent in control facilities. In the University of Utah project, there was an overall increase in the proportion of home dialysis patients in the experimental facilities of 6 percent, from 26 percent in May 1978 to 32 percent in May 1980. Of all new patients in the experimental facilities, 41 percent chose home dialysis compared to 29 percent in the control group. In the Research Triangle Institute demonstration, after the first 2 years of operation, the experimental home patient population increased from 31 percent in 1978 to 33 percent in 1980. Forty-eight percent of all new patients in the experimental facilities selected home dialysis rather than facility dialysis, and all new patients (only 3) in the control group selected home dialysis.

Experience after 2 years shows varied results with respect to the use of assistant versus partner aides in the experimental facilities. System Sciences reports that there has been an increase of 100 paid assistants and 65 paid partners in the experimental facilities. The University of Utah reports an increase of 33 assistants and 33 partners in the experimental facilities and Research Triangle reports an increase of 16 assistants and 49 partners in the experimental facilities. Further experience is needed to analyze the reasons for variations in the mix of paid assistants and paid partners.

The results of all three demonstration projects are being independently evaluated by the Orkand Corporation under a separate contract awarded in September 1979. Orkand's evaluation will focus on three main issues: (1) whether the availability of paid home dialysis aides increases the number of ESRD patients who choose to dialyze at home; (2) whether paid aides are cost effective to the Medicare program; and (3) whether paid home dialysis aides can be provided without adversely affecting the quality of care received by ESRD beneficiaries.

During 1980, Orkand collected data from a wide variety of sources. These data include a detailed cost report completed by each participating facility, which differentiated the cost of home dialysis from facility dialysis, Medicare billings, medical information system reports, and medical record assessments for all project patients. An analysis of these various data, together with interview survey results from a sample of patients and aides, will form the basis of the evaluation effort.

An interim evaluation report highlighting the first 2 years of the demonstration is expected to be available by April 1981. Interim reports of cost and quality issues will be available in April 1982, and the final report is scheduled to be published in October 1982.

In addition to the evaluation of the Paid Home Dialysis Aide Project, the Orkand Corporation is conducting a market study of ESRD equipment and supplies. Due to the rapid growth of the dialysis market and the important role that the government assumed in financing the cost of care for ESRD patients, it is important to study the marketplace in order to evaluate the nature of competition and to understand marketing strategies. This study will: (1) identify and describe the manufacturers and suppliers of dialysis machines, equipment, and supplies; (2) plot price trends for dialysis machines, equipment, and supplies; (3) estimate the potential for growth or shrinkage of the ESRD market; and (4) describe new technology which may affect the ESRD market. The final report will be published in September 1982.

Study of the Implementation of the End-Stage Renal Disease Program

In September of 1977, HCFA awarded a grant to the Rand Corporation to study the implementation of the ESRD program. The first objective of this project was to identify the major factors affecting the implementation of the ESRD program. The second purpose was to develop the administrative implications of the ESRD implementation experience for prospective national health insurance programs.

In September 1980, Rand published its final report. The report covers the period from the passage of P.L. 92-603 (October 1972) through mid-1978. It describes the process of implementation in two stages: the planning stage and the operational stage. It documents the design of the 32 ESRD Networks and discusses the problems encountered by the government in creating an efficient data system.

The report concludes that in many ways, the ESRD program is a success. Patients are receiving treatment, bills are being paid, and access to care is no longer an issue. In addition, the report suggests that the cost control experience is encouraging even though individual treatment costs are high. Although average per patient payments rose from $14,895 in 1974 to $20,149 in 1978, after adjusting for inflation using the consumer price index, there was "practically no increase" in payments. (The figure would actually decrease from $13,368 in 1974 to $12,170 in 1978 if it were adjusted for overall medical inflation instead of the consumer price index.)

The report attributes the success of the program to several factors: (1) the intent of Congress was relatively clear; (2) early reimbursement policies were sound; (3) patients exert a strong demand for an acceptable level of performance; and (4) competence is highest at the service delivery level where physicians and nurses operate treatment facilities.

In spite of the successes, the report indicates that there were problems in the implementation of the program. Additionally, the report concludes that there was a gradual decline, during the study period, in policy capability both in the Office of the Secretary and within HCFA.

ESRD Studies by Northwestern University

During FY 1980, Northwestern University completed three studies and developed three policy papers on issues relating to the ESRD program. In the first paper, entitled Compensation of Physicians in the End-Stage Renal Disease Program, Northwestern's authors argued that focusing on "fairness" with respect to physician reimbursement, and ignoring the larger issue of physician reimbursement as it relates to total program costs, is likely to be counterproductive in the program's efforts for general cost containment. The authors felt that some "overpayment" to physicians under the alternate (capitation) method of payment may be desirable if that slight "overpayment" offered incentives for a reduction in the overall costs of treatment. In order to determine the proper level of reimbursement under the alternative method which would act as an incentive for physicians while still reducing overall costs, it would first be necessary to document physician and non-physician costs under both methods of reimbursement (and of patient condition). Current data is not, however, sufficient to support this documentation.

The paper also suggested the following: (1) physicians are likely to have considerable discretionary power for performing non-routine services and, consequently, their ability to respond to incentives (in an effort to lower program costs) is likely to be great; (2) understanding the impact of physician reimbursement on the incentive for physicians to hospitalize patients is important in formulating reimbursement policies; (3) physician earnings under the alternative method do not appear to be grossly in excess of what might be determined as "fair" (consequently, time and motion studies of physician services in order to determine fair levels of payment are probably not worthwhile); (4) an analysis is needed on what constitutes the minimum level of services which physicians must perform to adequately care for their patients (particularly for physicians reimbursed under the alternate reimbursement methods);

and (5) an analysis is also needed on the physician's reimbursement incentives to foster or discourage home dialysis, or to accept or reject patients on the basis of their suitability for home dialysis.

In a second paper entitled Financial Incentives and Policy Goals of the End-Stage Renal Disease Program, Northwestern's authors have analyzed the relationship between the ESRD program's goals and the financial incentives inherent in the program. They conclude that the precise legislative intent regarding the goals of the ESRD program is not clear, particularly with regard to the overall objectives in treating patients. Whether a patient's health, general well-being, or some other objective is the focus of the program is not clear; consequently, there is considerable administrative discretion regarding the benefits of the program. This becomes important when evaluating costs and benefits borne by patients (such as travel costs) and the program's desire to use financial incentives to foster lower cost treatment therapies.

The paper also concludes the following:

1. The certificate of need (CON) requirement is unlikely to reduce program costs for center based dialysis given the current policy of charge reimbursement for dialysis services. The main consequence of CON is likely to be restricted entry of new providers with a reduction in market competition and reduced level of patient amenities;

2. Reducing reimbursement levels is likely to: (a) reduce the level of profits but not the level of patient amenities for the for-profit monopolist facilities; (b) reduce patient amenities but not profits for the for-profit and not-for-profit facilities in competition; and (c) reduce patient amenities and reduce efficiency for not-for-profit monopolistic facilities;

3. Minimizing budgetary costs without specification of goals concerning patient well-being or health status implies no limit to the cost which could be shifted from the budget to the patient;

4. A policy which would coax patients to shift from center to home dialysis without payment for home dialysis aides would probably be able to save program costs only by shifting costs from Medicare to the patient's family;

5. The social and budgetary costs of home dialysis experienced by patients currently dialyzing at home is probably a low estimate of the cost of home dialysis which would be incurred by patients currently dialyzing at centers if they were coaxed to dialyze at home.

In the final paper entitled An Economic Analysis of the Production and Cost of Renal Dialysis Treatments, Northwestern reported the results of an empirical analysis of the 1977 ESRD facility survey and the 1978 cost surveys. The analysis focused on the non-hospital dialysis facilities and was concerned with three issues: (1) whether there were differences in technical efficiency between for-profit and not-for-profit dialysis facilities and between facilities which compensate their facilities under the alternative or fee-for-service methods; (2) whether the amount of input per treatment decreases as the size of the facility decreases; and (3) whether dialysis facilities choose a mix of inputs (nurses, technicans, etc.) that will produce a given number of treatments at least cost.

The report provides the following conclusions:

1. For-profit facilities appear to use the same level of physical resource inputs (nurses, technicians, etc.) per patient as do the not-for-profit non-hospital facilities;

2. The cost of support services which facilities provide to patients who dialyze at home may be more substantial than generally believed. (A mean estimate per patient, per year for 1977-78 was $4,319);

3. Facilities which compensate physicians under the alternative method appear to have a substantial productivity differential when compared to facilities in which physicians are compensated on a fee-for-service basis. (However, the authors do not feel that these productivity differentials are real);

4. The typical dialysis facility uses too few dialysis stations compared to the amount of labor employed, based on a standard of cost minimization;

5. As facility size increases, cost per treatment declines. However, cost savings achieved by having larger facilities, compared to having several smaller facilities, imply greater indirect costs to patients who must travel longer distances to receive treatment;

6. An accurate and total assessment of the competition in the ESRD industry is not available but it is quite likely that the Certificate of Need requirement is a major non-competitive force because it limits entry of new providers into the market;

7. Free entry or competitive conditions would appear to be a desirable policy if the social goal is patient welfare rather than provider welfare, because it would translate into more convenient access to facilities for patients and reduced profits for providers. Free entry into the market would not decrease costs to the government but would shift benefits from providers to patients.

Study of Alternative Types of Therapy on ESRD Patients

HCFA awarded a 2-year grant, "The Impact of Alternative Types of Therapy on Patients with End-Stage Renal Disease," to Battelle Memorial Institute's Human Affairs Research Center in January 1981. The study will focus on several variables of interest to the program including an examination of quality of life, quality of care and cost of care to patients undergoing alternative types of therapy for treatment of end-stage renal disease. The study will also describe the extent of disability among dialysis patients and assess the potential for improving the lives of dialysis patients by changes in the types of therapy or through the provision of rehabilitation services. Four treatment modalities are included in the study: facility dialysis, home hemodialysis, continuous ambulatory peritoneal dialysis and renal transplantation. The research plan calls for a representative sample of patients from selected dialysis and transplant facilities to be interviewed through the use of telephone and mail survey instruments. Additional data will be collected from dialysis and transplant facilities, ESRD Networks and from the HCFA program files.

Separate models of the quality of life and quality of care of patients will be developed. Indicators of the quality of life will include patient socio-demographic characteristics, health status, functional limitations, work disability, social support, use of rehabilitation services, and type of therapy. Indicators of quality of care include hospital admissions, hospitalized days, physician visits, and patient mortality. Factors influencing quality of care which will be examined include patient characteristics, type of therapy, and structural features of the dialysis facility--quantities and characteristics of equipment and personnel used.

Study of the Non-Entitled ESRD Patient Population

HCFA, in collaboration with the ESRD Networks, will conduct an intramural study of the patients with end-stage renal disease who are not covered by Medicare. The study focuses on determining the number of non-entitled ESRD patients and the burden of their treatment costs. Person counts and total dollars billed will be collected on dialysis patients (in center and home dialysis) by primary source of support, which includes Veterans Administration, Medicaid, State ESRD program, private health insurance and self support. Information on the number of non-entitled transplant patients will also be collected. The study is expected to be completed during 1982.

The ESRD Program Evaluation Plan

In an effort to control the rising costs of the ESRD program, to improve the quality of services that ESRD beneficiaries receive, and to improve program management, HCFA, with assistance from the Office of the Assistant Secretary for Planning and Evaluation, has developed a comprehensive ESRD Evaluation Plan.

The goals and objectives for the Plan are to capture in one document the nature of the ESRD program and the evaluation issues that will be addressed in forthcoming initiatives. The specific objectives are:

1. To provide an overview of end-stage renal disease, the delivery system in which patients are treated and the nature of the health care financing program which Congress enacted in 1972 to help patients finance the high costs of this disease.
2. To provide a review of the current and completed research and evaluation studies which have been conducted, or sponsored, by the Health Care Financing Administration.
3. To identify and discuss the kinds of evaluation issues and questions that are being asked of the program.
4. To provide a conceptual and organizational framework for understanding and classifying the evaluation issues into study areas.
5. To perform a systematic analysis of each evaluation issue within the study areas.

The preparation of the plan involved a four stage process:

1. Reviewing the pertinent ESRD program documents with the intention of documenting expectations for the program and determining the implementation status of program activities. The review included selected articles and other published documents related to the legislative history, implementation and administration of the ESRD program and the functioning of the ESRD delivery system within the context of the general health care system.
2. Interviewing key governmental and nongovernmental individuals involved with the ESRD program in order to document program activities and projects underway, the results achieved, the legislative and administrative goals of the program and the expectations of the program from various perspectives. These interviews led to the identification of program objectives, information needs of program managers, a list of research and evaluation issues and questions, and the status of the administrative, research and evaluation projects that are currently being conducted or sponsored by HCFA and other agencies.
3. Classifying the research and evaluation issues that were identified through the literature review and interviews into an organizing matrix based on the various program modules that will be studied.
4. Formulating the evaluation plan by: developing the criteria, rationale and methodology for ranking the issues and proposed projects; grouping the projects into a matrix of current and proposed projects (cross-indexed to the relevant study areas); and, developing a management plan that related projects to staffing, funding and resource requirements that were consistent with the basic planning assumptions.

The evaluation plan discusses several cross-cutting issues related to the administration of the ESRD program. Along one dimension, the issues are arrayed against key program elements of access to care, quality of care and cost containment. Along the other dimension the issues are grouped into study areas that have a common theme. Study areas include: the congressionally mandated studies related to dietary controls and non-Medicare eligible patient populations; the management oriented program performance studies related to operations, monitoring and analysis; and the policy-oriented program impact studies related to the costs and benefits of different treatment modalities, the economics of the ESRD industry, the impact of new technologies and the international experience of ESRD programs in other countries. In total, 20 distinct projects are described in the evaluation plan. Fifteen of the projects are currently funded and these address many, but not all of the issues that have been identified. Five additional studies are contemplated to fill in those study areas where inadequate program information or knowledge exists.

Hemodialyzer Reuse

In P.L. 95-292, the Congress mandated a study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients. This requirement originated primarily from the fact that the procedure is employed with an estimated 16 percent of end-stage renal disease patients in the United States and, if expanded, has a large potential savings to the Medicare program. Within the Department, responsibility for the study has been divided between the National Institutes of Health (NIH) and the Health Care Financing Administration (HCFA), with the former undertaking the required clinical evaluations, and the latter assuming the lead on the financial and regulatory aspects.

NIH completed a preliminary, in-vitro study of dialyzer reuse which evaluated the efficiency of various reuse techniques. HCFA conducted a concurrent evaluation of the issue, which included an extensive literature review and meetings with interested parties in both the public and private sectors including patient groups, manufacturers, nephrologists, and involved Federal components. Action strategies are being planned for all of the potential options indicated by the NIH study and they will be implemented as soon as feasible.

Table 26A

MONTHLY DRUG COSTS FOR TRANSPLANT PATIENTS
TRANSPLANT CENTER A

	Immunosuppressives & Steroids	Supplements*	Subtotal, Immunosuppressives and Supplements	Antihypertensives	Total
Average costs, Users	$23.27	$4.34			$33.59
Range of Costs, Users	$4.74-$32.72	$1.28-$16.08	$4.74-$41.30	$1.64-$146.03	$18.54-$187.33 (all patients)
Percent of Users of all Patients	100%	31.2%		72.9%	
Average Costs, All Patients	$23.27	$1.36	$24.52	$24.50	$49.12

*Antacids not reported by Center A - see text

Table 26B

MONTHLY DRUG COSTS FOR TRANSPLANT PATIENTS
TRANSPLANT CENTER B

	Immunosuppressives & Steroids	Supplements	Subtotal, Immunosuppressives and Supplements	Antihypertensives*	Total
Average costs, Users	$58.59	$22.17	$81.00	$28.01	
Range of Costs, Users	$49.65-$66.15	$15.90-$37.20	$68.85-$103.35	$10.80-$77.10	$74.70-$145.95 (all patients)
Percent of Users of all Patients	100%	100%	100%	80%	
Average Costs, All Patients	$58.59	$22.17	$81.00	$22.41	$103.47

*Data not reported for diuretic drugs

TABLE 26C MONTHLY DRUG COSTS FOR TRANSPLANT PATIENTS TRANSPLANT CENTER C

	Immunosuppressives & Steroids	Antacids*	Total
Average Costs,	$21.84	$24.37	$46.21

*Reported as an inpatient cost - see text

TABLE 27A

RANGES OF REQUESTS FOR REIMBURSEMENT EXCEPTIONS
JANUARY 1 - DECEMBER 31, 1980

RANGE OF REQUEST	OUTPATIENT	TRAINING	PERITONEAL
Up to $150	33	0	0
$151 - 170	74	9	2
$171 - 190	64	17	3
$191 - 210	47	18	8
$211 and over	67	45	27
Totals	285	89	40

GRAND TOTAL: 414

TABLE 27B

RANGES OF APPROVALS (FULL OR PARTIAL APPROVALS)
JANUARY 1 - DECEMBER 31, 1980

		HOME	
RANGE OF APPROVAL	OUTPATIENT	TRAINING	PERITONEAL
Up to $150	47	0	1
$151 - 170	53	4	1
$171 - 190	52	12	4
$191 - 210	15	13	2
$211 and over	19	20	19
Totals	186	49	27

GRAND TOTAL: 262

RESEARCH*

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*Material in this section responds to:

Section 1881(g)(13) "the results of basic kidney disease research conducted by the Federal Government, private institutions, and foreign governments"

INTRODUCTION

Support of basic research in the kidney and urinary tract (KUT) area has shown an increase in both dollars and percentage of total funds, as shown in an analysis of NIH KUT research funding which compares the years 1976 and 1979. (See Tables 28A and 28B.) The categories of "normal structure and function" (which includes fundamental research into kidney diseases, many of which are responsible for ESRD) exhibit this increase, while research relevant to chronic renal failure and transplantation have been stable in dollar support. This latter represents a modest decline in percentage.

The remainder of this section presents the highlights of research supported by the Renal Physiology and Pathophysiology, Urology, and Chronic Renal Disease programs of the Kidney, Urology and Hematology Program, National Institute of Arthritis, Metabolism, and Digestive Diseases. Appendix D presents selected portions of the Summary Report of the International Transplantation Society, held in June 1980, in Boston, Massachusetts.

TABLE 28A

KIDNEY AND URINARY TRACT DISEASE RESEARCH FUNDED BY NIH - FY '79

Category	$Amount	% of Total ($)	No. of Projects	% of Total (No.)
Kidney Structure and Function	$26,551,169	38.21	378	30
Renal Disorders	$22,475,765	29.34	444	35.23
CRF and Tx	$12,323,639	17.73	240	19.04
Urinary Tract	$ 5,570,155	8.01	82	6.50
UTI	$ 1,188,215	1.71	22	1.74
Urolithiasis	$ 4,638,301	4.96	94	7.46

Source: Computer Retrieval of Information on Scientific Projects (CRISP), Statistics and Analysis Branch, Division of Research Grants (DRG), NIH.

TABLE 28B

KIDNEY AND URINARY TRACT DISEASE RESEARCH FUNDED BY NIH - FY '76

Category	$Amount	% of Total ($)	No. of Projects	% of Total (No.)
Normal Structure and Function -- Kidney	$13,215,426	28.5	294	26.8
Renal Disorders	15,493,262	33.4	346	31.5
Renal Failure	13,331,986	28.4	325	30.2
Urolithiasis	1,520,434	3.3	59	5.4
Urinary Tract	2,002,189	4.3	45	4.1
Urinary Tract Infections	1,012,922	2.2	22	2.0
Totals	$46,576,219	100.0	1,091	100.0

Source: Computer Retrieval of Information on Scientific Projects (CRISP), Statistics and Analysis Branch, Division of Research Grants (DRG), NIH.

RESEARCH ADVANCES
Kidney-Urology Program

o Isolated Glomerular Perfusion - a new investigative tool

In the past ten years, there has been substantial advancement in knowledge of the factors involved in the regulation of glomerular filtrate formation. Studies performed in many laboratories have demonstrated various hemodynamic and humoral factors which are involved in this process. Virtually all of such studies have been performed in a special group of rats, (Munich-Wistar), which have glomeruli accessible for micropuncture on the surface of the kidney. Thus, the vast majority of direct data concerning glomerular dynamics have been obtained from superficial nephrons of this breed of rats. Further, it is difficult to be certain in many of the reported studies whether the results obtained with a variety of pertubations are the consequence of a direct glomerular alternation or secondary to some systemic hemodynamic response. Lastly, it should be noted that glomeruli are not accessible on the surface of the dog kidney and that glomerular dynamic data available in this species have been obtained from more indirect methodology. With these points in mind, a technique was developed in the renal laboratory of Dr. J. H. Stein* and associates at the University of Texas Health Science Center, San Antonio, in which glomerular dynamics in the isolated dog glomerulus can now be measured in vitro.

With this technique, these investigators will be able to determine the effect of various pharmacologic agents on glomerular dynamics and to measure directly the glomerular ultrafiltration coefficient in normal and in pathophysiologic conditions. Further, this technique will make it possible to compare glomerular dynamics in superficial and juxtamedullary glomeruli for the first time.

Although the impetus to develop this method was to find a better means for understanding of the physiologic control of glomerular filtration, it appears that the most important application of this techique may be as a powerful tool to study the immunologic basis of renal disease. For example, it is known that many renal diseases occur as a consequence of the deposition of immune complexes within the glomerulus, but the mechanism(s) involved in the deposition of these immunogenic substances is not known. Prior to the development of this method, no methodology was available to directly evaluate in any isolated vascular bed the factors which lead to the extraction of immune complexes within the glomerulus. Future plans outlined by the group include investigations to determine the characteristics of a complex (i.e., size or charge) that are necessary for deposition within the glomerulus, and what pharmacologic agents (i.e., steroids, histamines, etc.) may modify this process. With these data, it is anticipated that the pathophysiologic basis of various renal diseases will be better understood.

*5 P01 AM 17387-07

o Golgi Apparatus - a secretory organelle

The Golgi Apparatus is a distinct and important membranous organelle of eukaryotic cells and is primarily involved in the process of secretion. Although much progress in unravelling the biochemistry and regulation of this organelle has been made since isolation has become routine, a great deal remains to be studied. Research in progress at Vanderbilt University under the direction of Dr. Becca Fleisher* is aimed at understanding: 1) how this membrane works to modify materials for secretion; 2) how it synthesizes cell constituents such as glycolipids; and 3) how it fuses with the cell membrane in the final step of secretion. Glycolipids are known to be involved in the immunologic specificity of tissues and may play an important role in the kidney transplantation rejection phenomena. In congential disease such as Krabbe's globoid cell leukodystrophy and in metachromatic leukodystrophy, where enzymes for the breakdown of certain glycolipids are lacking, the lipids accumulate in kidney tubules and are known to cause renal failure. The renal Golgi Apparatus is involved in the formation and secretion of proteins such as iallikrein, renin and erythropoietin, substances that play an important role in the control of blood pressure and of erythropoiesis. An extension of these studies should yield basic information relevant to health problems such as hypertension, heart diseases, stroke and anemia. Gaining a further understanding of molecular mechanisms of secretion also is relevant to such diverse problems as diabetes and cystic fibrosis.

*5 R01 AM 17223-05

o Urothelial-lined System - a model to study calcium oxalate crystallization

Dr. W. B. Gill* of the University of Chicago has reported that calcium oxalate, the major component in most human urinary calculi, is less likely to form in urothelial-lined systems than in the glass containers usually used to study precipitation phenomena. Dr. Gill and colleagues, participants in a NIAMDD sponsored Specialized Center of Research (SCOR), at Michael Reese Hospital and Medical Center, have developed a technique to initiate calcium oxalate crystallization in the catheterized bladder of anesthetized female rats, which they consider a "living test tube." Dr. Gill further has established that the state of the urothelium profoundly influences the characteristics of the stone forming process. For example, if urothelial injuries are induced, 1) calcium oxalate crystals are more likely to be nucleated at the site of injury, and 2) the crystals formed are more likely to adhere to the damaged urothelium than to a healthy bladder lining. Both of these phenomena are believed to be important in the initiation and progression of human stone disease. These experiments have led Dr. Gill to suggest that the nature of interface between the urine and the bladder wall, a factor neglected in most crystallization studies related to biological systems, may be more important than has been previously realized.

*5 P50 AM 20585-03
F.L. Cog, M.D.
Michael Reese Hospital and Medical Center
Chicago, Illinois

o Normal and Abnormal Prostatic Growth

A group under the leadership of Dr. Leland Chung* at the University of Colorado, Boulder, has developed a nude mouse colony in which human prostatic tissue can be grown with almost a 100% "take rate." Using this model the group is comparing the morphogenetic pattern of the prostate from both fetal and elderly human males. During 4 to 5 weeks of growth, the graft shows definitive signs of proliferation of epithelial cords and acinar development, which proceed to an advanced stage. To verify the hormonal responsiveness of these human prostate grafts, they initiated studies to evaluate the steroid receptor concentrations in these tissues by autoradiographic analysis. Preliminary results indicate that a nuclear androgen receptor is distributed over mesenchymal cell nuclei. By contrast, epithelial androgen receptors are completely absent during a comparable time frame. These findings are consistent with the concept that, during development, androgen receptor activity is present in mesenchyme. The workers postulate that the interaction between androgenic steroids and mesenchymal components of the prostate may account for morphogenetic and biochemical differentiation of this gland.

* ROL AM 25266-02

o Analytical Methodology for Measuring Oxalate in Urine

The majority of stones formed within the urinary tract in patients studied in the Western Hemisphere contain oxalate as the major anionic component. However, only a small percentage of these patients have a significant increase in urinary oxalate excretion. A major deficiency in the study of oxalate metabolism is the lack of a simple, reliable method of measuring oxalate in biological fluids. This has been an especial problem for routine clinical chemical laboratories which report large differences in oxalate levels from both normal and calcium oxalate stone forming patients, from laboratory to laboratory. The development of a single reliable method for measuring oxalate which can also be adapted to microanalysis by the renal physiologist was identified as a pressing need.

Under NIAMDD contracts, three research groups at different institutions are in the process of developing new methodologies for the accurate and precise determination of oxalate in human urine. Dr. J. H. Peters,* of SRI International, is pursuing an approach involving high pressure liquid chromatography (HPLC) separation of derivatives of oxalate with o-phenylenenediamine. Dr. H. A. Moye** at the University of Florida is using gas chromatography to identify oxalate as its bis-2-chloroethyl ester. This derivative is especially suitable for measurement by electron capture detection. Research underway at the Montefiore Hospital in Pittsburgh, Pennsylvania, involves the development of two separate methodologies. Dr. S. J. Yao*** is developing a method to analyze oxalate in urine without a derivatization step using HPLC coupled to an electrochemical detection system. Dr. Yao's other approach involves a carbon dioxide sensitive electrode coupled to an oxalate decarboxylase enzyme. To facilitate this endeavor, KD & U Staff have developed a plan for testing and comparison of each of these methodologies by providing a common pool of samples for each of the laboratories to analyze. Furthermore, a fourth laboratory which has a working oxalate method (which is both cumbersome and time consuming) has agreed to analyze these common samples for comparative purposes.

With techniques such as these to aid in the evaluation of a patient's potential for stone formation, the evaluation of the patient, and the need and effectiveness of therapy can be more effective.

* N01-AM-9-2213
** N01-AM-9-2212
*** N01-AM-9-2211

o Epidemiology of Urolithiasis

The primary objective of a case-control study at the Hospital of the University of Pennsylvania is the collection and analysis of data about risk factors suspected of causing or of influencing the incidence and prevalence of idiopathic urolithiasis. The basic question guiding the design of this study is: how do individuals with no known physiologic conditions predisposing to urolithiasis develop kidney stones while others do not? Dr. Stolley and his coworkers* have identified several areas which are of high priority, can be investigated, and readily lend themselves to research in the epidemiology of urolithiasis. These include: 1) investigation of specific potential or known risk-factors for urolithiasis such as obesity, unusual dietary habits, occupational history, use of medications (e.g., antacids and vitamin supplements), urinary tract infection, and others; 2) comparison of urinary electrolyte levels, especially calcium, in patients who form kidney stones and in controls who do not form stones, in order to derive a more precise range for "normal" calcium excretion, and identification of common factors and trends among the hypercalciuric patient group.

Thus far they have developed a "risk-factor profile" questionnaire which was pilot-tested, refined, and already has been administered to 95 patients with idiopathic urolithiasis, and to 80 community and clinic controls. In addition to these interviews, two 24-hour urine samples are collected by each study member after a 5-day period of restricted dietary calcium carbonate to achieve a total daily intake of 900 mg. calcium. The analysis of these 24-hour urine samples are analyzed and excretion rates of Na, K, Ca, phosphate, oxalate, uric acid and creatinine are calculated. The incidence of hypercalciuria in their sample of controls obtained to-date is: 14 percent in the clinic controls, 15 percent in the high school faculty controls, and 30 percent in the controls from Hershey Foods Labs. The frequency of hypercalciuria as reported above differs from that of a previous report in the literature: "less than 5 percent of otherwise normal people" (Coe, F.L., Nephrolithiasis, pg. 72, Yearbook Medical Publishers, Inc. Chicago, 1978). However, a long-term follow-up of the controls found to be hypercalciuric must be completed.

*AM 23094

- Mechanism of Abnormal Drug Binding in Uremia is Advanced

Studies of plasma from patients with renal failure have shown defective binding of many drugs and several endogenous substances. The degree of binding inhibition for some drugs is of such a magnitude in patients with advanced uremia that modification of drug administration may be required. Much effort has been directed toward identification of individual drugs whose binding is critically impaired. Few investigations have been directed toward determining the nature and causes of this binding inhibition. Although several plasma proteins are known to bind a variety of drugs and other substances, the plasma most prominent in this role is albumin. Reduced binding is found in patients with renal failure as compared to normals with equal albumin concentrations. This binding defect has been postulated to result either from alteration of the primary structure of albumin or from accumulation of an unknown solute which interferes with binding.

Dr. Paul Gulyassy and his associates at the University of California have studied a model drug system, binding of phenytoin by both normal and uremic plasma. The objective was to isolate the inhibitor(s) of phenytoin binding. An alcohol extract of a crude inhibitory component was isolated successfully by a complex separation process. Preliminary characterization shows it is a molecule less than 10,000 daltons, is bound tightly to albumin at pH 7-8, and is not a long chain fatty acid.

The isolation of a crude inhibtor of drug binding to albumin is a significant step toward understanding this abnormality in uremic patients. It could aid the clinician in prescribing appropriate drug dosages.

References:

Grant Am-19833. Ref. Depner, T.A., Sanfel, L.A., Jarrard, E.A., and Gulyassy, P.F.: Improved Plasma Phenytoin Binding in Uremia. Effect of in vitro acidifications and Anion Exchange Resin. Nephron 25:5, 231-7, 1980.

Gulyassy, P.F., et al, Abnormal drug binding in uremia. Dialysis and Tra

Transplantation: 81:1, 19-23, 1979

Gulyassy, et al. Manuscript, submitted to Kidney International 9/13/79

- Partial Structure of a Uremic Middle Molecule has been Determined

The search for a uremic toxin(s) has not been fruitful, while numerous substances are known to accumulate in the body fluids of patients with uremic symptoms.

There has been a poor or no correlation between the toxic manifestations of uremia and the levels of creatinine, urea, uric acid, and a myriad of other substances measured in plasma. This discrepancy between the accumulation of measured small molecules, and the occurrence of uremic symptoms, was most obvious in patients treated with long-term peritoneal dialysis who, in spite of relatively inefficient dialysis of small molecules, were doing well and did not develop neuropathy. As a result of these observations, Scribner and Babb originated the middle molecule hypothesis. Few new theories in nephrology have evoked so much interest and created so much confusion as the middle molecule hypothesis.

In the last seven years Dr. Jonas Bergstrom and Peter Furst and their coworkers at St. Eriks hospital and the Karolinska Institute, in Sweden, have devloped a methodology for separation and analysis of certain higher molecular weight abnormal substances appearing in uremic sera. These investigators have determined a partial structure of one of the most plentiful abnormal solutes designated as peak "7C".

The substance is a glycyl oligopeptide, approximately 30 percent glycine by weight. The compound has glycine in the C-terminal position and no N-terminal amino acid. It is postulated that it has an acidic group separable by hydrolysis from a second blocking group, which is joined to the glycine chain. Determination of the structure of this substance and other higher molecular weight, abnormal, uremic solutes will aid markedly the understanding of critical, metabolic anomolies of uremia.

Contract N01 AM-2-2215 References

Annual Report "A Study of Uremic Toxicology," NIH Contract N01 AM-2-2215, February 28, 1979.

J. Bergstrom and P. Furst: Uremic Middle Molecules; Clinical Nephrology 5(4) 143-52, 1976.

L. Zimmerman, P. Furst, J. Bergstrom and H. Jorrnvall, A New Glycine Containing Compound With a Blocked Amino Group from Uremic Body Fluids. Clinical Nephrology. 14(3). 107-11, 1980.

- Use of Both 24,25 and 1,25 - Dihydroxyvitamin D3 assists patients with dialysis osteomalacia resistant to 1,25 alone

Between 10 and 25 percent of patients with long standing renal failure have overt skeletal disease. Prevention of these abnormalities is preferred to initiating treatment after the onset of severe disability or permanent deformity.

Treatment with 1,25 - dihydroxyvitamin D3 (1,25) is effective in reversing many manifestations of the marked secondary hyperparathyrodism commonly present in patients with advanced renal failure and/or undergoing hemodialysis. Observations that elevated plasma levels of PTH were reduced to normal in uremic patients treated with 1,25 suggest that this sterol might be effective in preventing the development of overt secondary hyperparathyroidism. The physiological role of 24,25 dihydroxyvitamin D3, (24,25), a naturally occurring Vitamin D sterol produced by the kidney, is uncertain. Because of its possible effect in enhancing bone mineralization, Dr. Coburn and his group gave 24,25 to 13 dialysis patients, who had osteomalacia, no hyperparathyroidism and hypercalcemia, and who exhibted no clinical improvement with either drug alone. In contrast, combined therapy with 24,25 plus either 1,25 or DHT led to clinical improvement in six patients with a consequent lowering of serum calcium and alkaline phosphatase. Bone biopsies repeated in three patients revealed a decrease in osteoid volume. Also, when given with 24,25 the tolerated dose of 1,25 was significantly higher. These results do not define a physiological role for 24,25, but show that the sterol has clinical applicability as an adjunctive pharmacological agent for the enhancement of bone mineralization in some cases resistant to 1,25 alone.

Reference:
Contract: Am 7-2204, Univerisity of California, Los Angeles Prophlactic use of 1,25(OH)2D3 for renal osteodystrophy in patients under hemodialysis.

Abstract for the American Federation for Clinical Research #532A - May 10-12, 1980

- Assessment of Nutritional Status and Caloric Supplementation Aids Growth of Children with Chronic Renal Insufficiency.

Nutritional deficiencies in children have been linked to their impaired growth and diminished muscle mass. However there are no standards for the assessment of nutritional status in children with chronic renal insufficiency.

Dr. Holliday determined the biochemical indices of body protein mass, anthropometric measurements and caloric intake over a three year period in 20 uremic children. Each child received caloric supplementation during only one year of the study. With caloric supplementation, the energy intake rose from 77 percent to 99 percent of recommended dietary allowance and growth rates increased from 70 percent to 95 percent of values expected for the patient's age. In the third year of the study, when the children were allowed to choose their own diet, caloric intake decreased to control levels and anthropometric indices regressed.

It was concluded that anthropometric measurements are a reliable and reproducible indicator of moderate energy deprivation in children, and that caloric supplementation does improve these indices.

Reference:
1 R01 AM 25204-01A1; University of California, San Francisco, Abstract ASN Nov. 18-18-20/79

- Techniques for Microwave Thawing of Frozen Preserved Kidneys Improved

Long term cryopreservation of organs could be a means of overcoming the shortage of donor organs for renal transplantation. A technical problem that needs to be overcome is the difficulty in achieving uniform, rapid thawing of cryopreserved organs. In freeze-thaw studies, Dr. Richard Lillehei and associates at the University of Minnesota, found that very rapid thawing rates were associated with less damage in slowly frozen organs. This study evaluated various techniques of microwave thawing of frozen canine kidneys.

Dr. Lillehei observed that use of a relatively high microwave frequency at high power for initial thawing from very deep subzero temperatures to near -20 C, and then a lower radiofrequency to near zero, minimized burning of the surface of the organ. Although with subsequent reimplantation, function was not established in any such cryopreserved kidney, the techniques have allowed for high thaw rates with minimal thermal runaway. The ability to thaw frozen organs at reasonable high rates in a uniform manner is expected to greatly facilitate the study of other aspects of freeze-thaw damage to cryopreserved organs.

Reference:
5 R01 AM 16830-05, Abstract for Central Surgical Association 3/5-7/81, submitted 9/12/80.

- Antilymphoblast Globulin (ALG) under Prospective Controlled Test for Effectiveness in Renal Transplantation

Of critical importance in renal transplantation is control of the recipient's immune response so that the allograft is not destroyed. Dr. John Najarian and his associates at the University of Minnesota are conducting a cooperative prospective double blind study to evaluate the efficacy of Minnesota ALG (antilymphoblast globulin) as an immunosuppressive adjunct in first cadaver renal transplant patients. Five hospitals are participating in the study. Patients are randomized to receive either human serum albumin, or equine ALG, intravenously for fourteen days at 30 mg/kg/day. Patients are stratified by age (greater than 40 or 39 or younger); histocompatibility match (two or more matches and less than two); and transfusion status (transfused or not). Imuran and Prednisone are administered to all patients in the study.

Preliminary results of the trial are as follows: as of May 1980, 150 patients entered the trial with 132 being randomized, 65 to placebo and 67 to ALG. For 72 patients with a history of blood transfusions, graft function in the ALG group was 76 percent compared to 58 percent for the placebo. Patient survival was 86 percent in the ALG group versus 81 percent for the placebo.

The final analyses will separate the influence of age, histocompatibility match, and transfusion status and ALG as an adjuctive therapy on both graft and patient survival.

Grant P01-AM-13083, Reference. Annual Progress Report, June 27, 1980

- Cimetidine Lowers Serum Parathryoid Hormone (IPTH) in Chronic Renal Disease

Dietary phosphorus restriction and/or antacids can prevent or reverse uremic hyperparathyrodism partially, but this therapy is difficult to maintain on a long term basis. Vitamin D metabolites lower iPTH but often at the risk of hypercalcemia. Dr. Bourgoignie has found that Cimetidine, an histamine receptor antagonist, decreased circulating iPTH in ESRD patients, maintained on chronic hemodialysis.

In his study, seven normo-orhypocalcemic patients were given oral Cimetidine for 10 weeks. IPTH fell in all patients (from 382 to 107 ul/eg/ml) (normal values are less than 75 ul/eg/ml) and the inhibition of iPTH generally became apparent after two to three weeks of treatment. Two weeks after discontinuation of Cimetidine, iPTH returned to 55 percent of pretreatment values, and serum calcium, phosphorus and magnesium did not change significantly. In contrast, in a hypercalcemic patient, serum calcium fell from 14.5 to 10 mg% within one week of Cimetidine. Cimetidine appears to offer a new therapeutic approach to uremic hyperparathyrodism.

Reference:

5 R01 AM 19822-05, University of Miami, Abstract for ASN - 11/18-20/79

- o Lack of Influence of B-lymphocyte Cross Matches on Outcomes of Renal Transplants

A negative serologic cross-match between recipient serum and donor lymphocytes was a standard requirement for clinical renal transplantation, because a high incidence of hyperacute rejection occurred if transplants were performed when a positive cross-match was present, and an unfractionated donor lymphocyte preparation was used.

Dr. Ettenger and his co-workers found that a positive unfractionated cross-match is not a contraindication for transplantation, since when fractionated, a positive cross-match against donor B, (but not T), lymphocytes is not associated with early irreversible rejection. Over a 2 1/2 year period, they followed 45 cadaver renal transplant patients in whom prospective standard B and T lymphocyte cross-matches were performed. Their data indicate that presensitization with antibodies against donor B lymphocytes neither adversely nor beneficially affects transplant outcome. Therefore, a positive B lymphocyte cross-match is not deleterious to long term graft outcome.

A weakly positive cross-match with unfractionated lymphocytes may be due to anti-B lymphocytes only, and could be used as a contra-indication to transplant, if the results of the cross-match are not known in an unfractionated manner. Transplantations could be performed in greater number in the face of a positive cross-match with less chance of acute rejections, as long as B lymphocytes are the ones identified in the positive cross-match.

Reference:

Ettenger: 5 KO8 AM 00597-02, University of California, Los Angeles Transplantation proceedings Vol XI No. 1 (March 1979)

- o A New Technique to Study the Functional Profile of the Isolated Uremic Nephron is Developed

Studies of renal metabolism must take into consideration the fact that the kidney is a heterogenous organ with structurally, functionally, and metabolically distinct components. An ionization chamber method, utilizing isolated segments of the nephron, where substrate oxidation (14 C- 14C02) is instantaneously and continuously measured, has been developed by the UCLA group. In utilizing this technique, Dr. Fine and his group have observed distinct metabolic differences between various segments of the nephron. Their findings show a significant pentose phosphate pathway in cortical collecting ducts. This technique which utilizes a vibrating reed electrometer and ionization chamber for the measurement of minute quantities of radioactivity, is capable of measuring the metabolic activity of individual segments of a single nephron, continuously. It might be possible to combine this technique with that of microperfusion to allow simultaneous measurements of transport and metabolism.

Reference:
5 KO4 AM 00585-04

Abstract for the ASN Nov 18-20/1979

- o Antibodies Reactive with Donor Vascular Endothelium Shown to a Highly Predictive of Renal Allograft Rejection

The survival of clinical renal transplants is imperfect, with approximately 25 percent of living related donor and 45 percent of cadaver donor allografts being lost from irreversible rejection. Histocompatibility testing of potential recipients of donor kidneys is conducted by studies of lymphocytes of the two individuals. During the past 6 years, Dr. James Cerilli and colleagues at the Ohio State University have analyzed the clinical significance and specificity of an antigen system found on the vascular endothelial cell, but not present on lymphocyte or renal cells. Dr. Cerilli has found that this antigen system demonstrates a high correlation with the clinical course of patients undergoing a renal transplant. Essentially all patients who had antivascular endothelial cell antibody before, or developed it after, transplantation lost their grafts from rejection. The Ohio State investigators, and others, have shown that this antigen system (abbreviated VEC for vascular endothelial cell) is different from the conventionally used HLA-A tissue typing system. It is also different from HLA-B, HLA-C and DR systems.

The correlation found between VEC antibody and the subsequent clinical course of the transplant is notable. Sera obtained before transplantation were analyzed for the presence of antivascular endothelial antibodies against a panel of VEC obtained from umbilical veins and intercostal arteries. In some instances, patient sera were analyzed for the presence of antivascular endothelial antibody to VEC of the specific donor by using the intercostal artery of the donor obtained at the time of donor nephrectomy. Activity to VEC was compared to reactivity against a panel of lymphocytes from 40 to 50 random donors. Examination of outcome data revealed that 85 percent of the patients with antibody to VEC panels but not to lymphocte panels experienced graft rejection (50 percent in an accelerated fashion). A positive VEC reaction before transplantation was associated with a high incidence of graft failure, particularly early graft failure. In preliminary studies, it was found that positive reactions against donor vascular endothelial cells are associated with an 82 percent graft loss, usually from accelerated rejection.

The findings of this study are a significant step toward the important goal of being able to predict immunologic graft rejection, and thus improve kidney transplantation as a successful treatment modality for the chronic renal failure patient.

Grant R01 AM 16804

Reference:
Cerilli, J. Brasile, L., "Endothelial Cell Alloantigens," Tranpslantation Proceedings, XII, No. 3, Suppl. 1, 37-42, 1980

NETWORK ACTIVITIES*

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*Material in this section responds to:

Section 1881(g)(14) "information on the activities of medical review boards and other Network organizations"

INTRODUCTION

Section 1881 of the Social Security Act mandated the establishment and support of End-Stage Renal Disease (ESRD) Networks to coordinate the provision of quality care and the efficient distribution and utilization of resources in the delivery of kidney dialysis and transplantation services. Regulations published on June 3, 1976 at 42 CFR 405.2110 through 405.2114 provided for the designation of Network areas and Network Coordinating Councils to accomplish this purpose; 32 such areas and councils have been designated. The Networks are non-profit, voluntary groups composed of one representative from each area dialysis and transplant facility, and a number of at-large members representing ESRD patients and other social, medical, or technical disciplines involved in the delivery of care. Since 1979, all Networks have been operational in coordinating area activities in their three major areas of responsibility: quality of care review, planning, and exchanging data and information.

Total funding for Networks increased from $4.5 million in 1979 to $5.3 million in 1980, while the total number of ESRD patients rose from 49,583 to 57,061. The increased overall funding level resulted in the continued development of activity in the functional areas mentioned above as well as some expansion in special initiative activities such as patient rehabilitation and education programs.

Though the Networks have, in certain instances, improved program operations, their experience for the most part has demonstrated their inability to fulfill their mandated responsibilities. The Department, after careful consideration of the experience with the Networks, is proposing that all Networks be abolished in FY 1983.

QUALITY OF CARE REVIEW

The primary activity in conducting quality of care review continued to be the performance of Medical Care Evaluation studies (MCEs). All 32 Networks were involved in the performance of at least one MCE during 1980, with some Networks completing three MCEs and others reporting quality of care improvements following re-audits of earlier studies. This year's MCEs evidenced an encouraging orientation towards problem solving rather than statistical compilation without follow-up on findings. However, Networks continued to avoid quality review studies in difficult or controversial areas of patient care. Only a few took an indepth look at patient care plans and the requirement that all patients be periodically reviewed to determine their suitability for self-care or transplantation. There is very little evidence to show that Network MCEs had any effect on increasing referrals for these two treatment modalities. In fact, quite a few Networks actually showed decreases in the percentage of patients either treated at home or transplanted.

We continued to see much of the quality review activity directed at such issues as hepatitis prevention, water standards, or dialysis equipment comparisons, rather than at more controversial issues such as mortality rates, cadaver kidney graft outcomes, or patient rehabilitation status. Although all areas cited are important components of quality care review, after 3 full years of operations, it was anticipated that the Networks would focus their studies more on the critical area of patient outcomes rather than on structure or process criteria.

Most Networks do not appear to have taken a very aggressive stance in monitoring or reviewing complaints about the quality of care. For example, one type of complaint is particularly disturbing. The complaints concern facilities "shortchanging" dialysis times for patients to accomodate more patients on a given shift. These allegations note that patients are removed from dialysis when their "time is up", rather than when clearances and other physical signs would indicate removal. Further, HCFA continues to receive complaints that patients are not being offered all possible treatment modalities. While HCFA has offered workshops to assist the Networks in performing various aspects of quality review, we feel that there continues to be resistance on the part of Networks to directly confront the difficult issues.

PLANNING FOR FACILITY CERTIFICATION AND EXPANSION

Networks serve in an advisory capacity to State and Federal agencies in reaching final decisions regarding the expansion and certification of ESRD facilities. Initial Network activity primarily involved the development of facility planning criteria and standards for evaluating the need for new or expanded facilities. During 1980, only a few Networks began to play an expanded role in the facility certification process through the analysis and distribution of patient specific data to the various health planning agencies in their areas.

Some Networks worked to alleviate the general lack of understanding among providers and the public regarding the roles of the various State and federal health agencies involved in the facility certification process. Networks continued to publish and distribute Certificate of Need manuals to clarify the application procedure and the roles of agencies involved in review of the applications. They also took part in reviewing staff qualifications of new facilities with an eye towards the prevention of potential conflicts of interest. One final facet of some planning functions involves distribution of scarce resources, such as skilled home-care training personnel or services for hepatitis-suspect or transient patients.

DATA

As previously mentioned, Networks play a role in the exchange of data and information among agencies responsible for health planning and quality assurance activities for ESRD patients. Another facet has been continued work with providers to assure greater compliance in submitting the national Medical Information System (MIS) forms. Finally, a growing number of Networks implemented individual data collection systems needed to improve the quality of patient care and comparative facility performance in their areas. By the end of 1980, approximately half of all Networks had either implemented their own data systems or submitted acceptable proposals to receive funding to do so.

SPECIAL INITIATIVES

Rehabilitation and education have always been an integral part of the Networks' responsibilities in the patient care area. However, these activities have often been overshadowed by other facility and physician interests. We have been encouraging the Networks for sometime to increase emphasis on patient issues. Although not all have improved their efforts in this area, many have. Following is a list of some special initiative activities reported by various Networks in 1980:

1. Establishment of committees or task forces focusing on care provided to patients by social workers and or dieticians;

2. Development and distribution of model patient long term care plans, including statements of patient rights and responsibilities;

3. Communication with State Vocational Rehabilitation Agencies in order to promote improved access by ESRD patients;

4. Publication and distribution of booklets designed to improve the educational materials available to ESRD patients;

5. Establishment of disaster preparedness plans, conduct of studies on patient transportation options, and in one case implementation of an emergency transportation system during a mass transit strike;

6. Involvement in the development and implementation of innovative programs such as a Kidney Line telephone service and a Kidney Olympics; and

NETWORK OBJECTIVES

As part of the newly introduced funding application process for 1981, Networks were required to establish measurable objectives which addressed the ESRD program priorities and to include specific methodologies for accomplishing the objectives. The statutory program priorities addressed by the objectives are as follows:

1. Encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient;

2. Developing criteria and standards relating to the quality and appropriateness of patient care, and Network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

3. Evaluating the procedure by which facilities and providers in the Network assess the appropriateness of patients for proposed treatment modalities;

4. Identifying facilities and providers that are not cooperating toward meeting Network goals and assisting such facilities and providers in developing appropriate plans for correction; and

5. Making recommendations with respect to the need for additional or alternative services or facilities.

Statistics for 1980 on home dialysis and transplantation reflect gross increases in the total number of ESRD patients on these legislatively preferred modalities. However, in many cases, these increases are exceeded by the overall growth of the ESRD population, resulting in net decreases in the proportion of patients treated by one or the other of these modalities. Please consult the "Dialysis" and "Transplants" sections of this report for individual Network statistics on gross increases or decreases in treatment modalities.

The tables below compare individual Network net changes for 1980 in the percentage of home dialysis and transplant patients, grouped according to each Network's 1979 percentage treatment rates. A brief discussion of the information presented follows the tables.

TABLE 29A

COMBINED UTILIZATION OF TRANSPLANTATION AND HOME DIALYSIS

% of Combined Transplant + Dialysis Pts. in 1979	Network With Increases More Than 2 Percent	Networks With Increases Less Than 2 Percent	Networks With Decreases Less Than 2 Percent	Networks With Decreases More Than 2 Percent
50 - 60			7, 16	2
40 - 49.9	13			
30 - 39.9	5, 8	9	21	
20 - 29.9	14, 18	22, 26	6, 10 17, 20	1, 30, 31
10 - 19.9	4, 12, 19 23, 27, 28 29	3, 15 24, 25	11, 32	

TABLE 29B

UTILIZATION OF HOME DIALYSIS

% of Home Dialysis Patients in 1979	Networks With Increases More Than 1 Percent	Networks With Increases Less Than 1 Percent	Network With No Change	Network With Decreases Less Than 1 Percent	Networks With Decreases More Than 1 Percent
40 - 50			2	16	
30 - 39.9				5	
20 - 29.9	8, 9, 21	7			
10 - 19.9	6, 10, 11, 13 14, 18, 22, 24	17		20, 32	1, 26 30, 31
0 - 9.9	3, 4, 12, 19 23, 25, 27, 28 29	15			

TABLE 29C

UTILIZATION OF TRANSPLANTATION

% of Transplant Patients in 1979	Networks With Increases More Than 1 Percent	Networks With Increases Less Than 1 Percent	Network With No Change	Network With Decrease Less Than 1 Percent	Networks With Decreases More Than 1 Percent
25 - 30					7
20 - 24.9				13	
15 - 19.9		8			
10 - 14.9	26	3, 22		9, 14, 17	2, 6, 21, 31
5 - 9.9	5, 12, 18, 28	4, 15	23, 24, 27	25	10, 11, 16 20, 30
0 - 4.9	19	29		32	1

As noted in the overview of this report, we estimate an optimum home dialysis and transplant population of approximately 56 percent of total ESRD patients. These tables appear to corroborate this estimate in that all three Networks with combined home dialysis and transplant populations of over 50 percent were unable to further increase these populations. Correspondingly, four of the five Networks with combined rates between 30 and 50 percent evidenced continued increases in the total percentage of patients on these modalities. We are concerned to note, however, that seven of the eleven Networks with combined rates in the 20 to 30 percent midrange showed decreases in the total percentage of home dialysis and transplant patients. Two of the thirteen Networks in the lowest combined rate grouping (10 to 20 percent) also experienced decreases in the total home dialysis and transplant percentage. We plan to look closely at the performance of these nine Networks in meeting their 1981 objectives for increasing the percentage of home dialysis and transplant patients.

The tables separately depicting utilization of home dialysis and transplantation reflect the overall trend towards increased use of home dialysis and a leveling off in the percentaage of transplant patients. The continued growth in popularity of CAPD appears to be a significant contributing factor to this trend, although further analysis is necessary to reach any definitive conclusions.

All three Networks where the percentage of home patients exceeded 30 percent showed no change or insignificant decreases in this percentage. It is encouraging to note that the four Networks in the 20 to 30 percent home dialysis range all managed to further increase this population percentage. Similarly, 20 to 30 percent seems to be the maximum transplant rate currently achievable in that both Networks in this category showed small decreases in 1980. We are most concerned, once again, with the six Networks in the 10 to 20 percent home dialysis category which experienced decreases in this percentage during 1980, and with the fact that 15 Networks in the low transplant percentage categories also showed decreases.

FIVE-YEAR PROJECTIONS*

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*Material in this section responds to:

Section 1881(g)(15) "estimated program costs over the next five years"

PROJECTED ENROLLMENT AND BENEFIT PAYMENTS FOR THE END-STAGE RENAL DISEASE PROGRAM

Medicare enrollment for persons with ESRD is projected to increase from 72.8 thousand in fiscal year 1982 to about 86.7 thousand by fiscal year 1986. Medicare benefit payments for these persons are projected to increase from $1.8 billion to about $2.8 billion for the same period of time. The year to year changes are the result of the interaction of two factors: (1) increases in the population, including changes in the mix of treatment modes, and (2) increases in the cost of the services provided. The table below shows the projected enrollment and benefit payments on a cash basis through fiscal year 1986.

TABLE 30

ESTIMATED ENROLLMENT AND AGGREGATE BENEFIT PAYMENTS ON A CASH BASIS TOTAL ESRD MEDICARE PROGRAM[1]

Fiscal Year	Average Annual Enrollment (thousands)	Total Benefit Payments (millions)
1982	72.8	$ 1.8
1983	76.8	2.0
1984	80.5	2.3
1985	83.7	2.5
1986	86.7	2.8

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[1] Based on the economic assumptions in the Mid-session Review to the 1982 Budget. It includes total expenditures for all ESRD beneficiaries including ESRD related benefits and non-ESRD related benefits. It does not include the effects of proposed regulations on incentive reimbursement and Medicare being second payer for certain ESRD benefits.

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APPENDIX C - CLASSIFICATION OF ESRD FACILITIES AS DEFINED BY SUBPART U, 42 CFR 405.2100, ESRD UTILIZATION

An ESRD facility (Renal Dialysis Center - RDC, Renal Dialysis Facility-RDF) which meets all other conditions for coverage of ESRD services is classified according to its utilization as follows: unconditional status, conditional status, or exception status.

If the facility meets the utilization requirements for unconditional status, this status remains as long as the facility continues to meet the requirements. If the facility meets the utilization requirements for conditional status, this status also remains as long as the facility continues to meet the requirements.

Effective with the implementation of the long-term ESRD regulations (September 1, 1977), facilities entering the program had one year to achieve conditional status and two consecutive years in which to achieve unconditional status. However, under regulations published on September 2, 1980 (effective January 1, 1980) these time periods were extended to two and four years, respectively.

Under unusual circumstances, the Secretary may grant an exception for a limited time, not exceeding one year, to a facility which is not in compliance with the minimum utilization rate(s) for dialysis. This exception may be granted where rigid application of minimum utilization rate requirements would adversely affect the achievement of ESRD program objectives.

Facilities which do not meet at least one of the above classifications will not be eligible for reimbursement for that ESRD service. The utilization standards for renal dialysis facilities (RDFs) are:

(1) For any facility located within a standard metropolitan statistical area of 500,000 population or greater:
    (a) Unconditional status - six or more dialysis stations with performance of an average of 4.5 or more dialyses per station per week.
    (b) Conditional status - six or more dialysis stations with performance of an average of between 4.0 and 4.5 dialyses per station per week, or four or five dialysis stations with performance of an average of 4.5 or more dialyses per station per week.

(2) For any facility located in a standard metropolitan statistical area of less than 500,000 population, or in an area not included in a standard metropolitan statistical area:
    (a) Unconditional status - three or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week.
    (b) Conditional status - two dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

Renal Dialysis Centers - RDCs

The utilization standard for Renal Dialysis Centers performing greater than 20 percent of their dialyses on outpatients:

(1) For any facility located within a standard metropolitan statistical area of 500,000 population or greater:

   (a) Unconditional status - six or more dialysis stations with performance of an average of 4.5 or more dialyses per station per week.
   (b) Conditional status - six or more dialysis stations with performance of an average of between 4.0 and 4.5 dialyses per station per week, or four or five dialysis stations with performance of an average of 4.5 or more dialyses per station per week.

(2) For any facility located in a standard metropolitan statistical area of less than 500,000 population, or in an area not included in a standard metropolitan statistical area:
   (a) Unconditional status - three or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week.
   (b) Conditional status - two dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

The utilization standard for Renal Dialysis Centers performing 20 percent or less of their dialyses on outpatients:

(1) Unconditional - three or more dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

(2) Conditional - two dialysis stations with performance of an average of 4.0 or more dialyses per station per week.

APPENDIX D - SELECTED PORTIONS OF THE REPORT OF THE VIII INTERNATIONAL CONGRESS OF THE TRANSPLANTATION SOCIETY: Boston, MA--June 29 - July 4, 1980

Organization: A total of 669 abstracts were submitted for consideration. Abstracts were allocated to one of the five groups according to topic and distributed to each member of the specific panel of reviewers for that topic. Abstracts were scored in blind fashion using the NIH scoring system of 1 (highest) to 5 (lowest) rating system. Scores were averaged and abstracts were ranked. A total of 292 abstracts were selected for presentation. These were distributed as follows: 5 in Plenary sessions, 49 in Symposia, 148 in Forum sessions, and 90 in Poster sessions. The lowest score for any abstract selected in any topic group was 2.8. Extreme care was taken to select abstracts for each topic in such a way as to reflect the total number of abstracts submitted for that particular topic.

Dedication: The Congress was dedicated to Professors Jean Hamburger, John Putnam Merrill and Joseph E. Murray.

Summary of Proceedings: The following is a summary of the general topics presented at the Congress. A detailed proceedings of the Congress (total 1,400 printed pages) will be published as Transplantation Proceedings, VIII International Congress of The Transplantation Society, Anthony P. Monaco and Mary L. Wood, editors, in March 1981 by Grune and Stratton, New York.

Clinical Transplantation

A. Kidney Transplantation

Results and General Considerations: Major progress in kidney transplantation has been in increasing use of cadaver kidneys as the concept of brain death has gained wide acceptance. Improvement has been seen in patient survival (79 percent) and graft survival (50-60 percent) at one year as transplantation units have accepted that heavy immunosuppression will not alter irreversible rejection. Judicious use of transplant biopsy has led to early recognition of irreversible rejection, abandonment of immunosuppression and the graft, return to dialysis to await the possibility of a subsequent graft. Preservation of kidneys harvested from cadaver donors has continued to use machine preservation for periods up to 72 hours, or ice storage, after initial flushing with cold electrolyte solutions, for periods up to 36 hours. Both methods provide adequate time for typing, cross-matching, etc. Methods for long term preservation are still not available. Cardiovascular and cerebrovascular complications have replaced infections as the major cause of death post-transplantation. Infection remains a serious problem with cytomegalovirus infection emerging as a source of great concern. Evidence now exists that transplantation of a kidney from a sero-positive donor to a sero-negative recipient should be avoided. Although malignant tumors post-transplantation (see below) continue to occur, the increased risk of spontaneous neoplasms is not sufficient to contraindicate transplantation. Steriod complications (diabetes, avascular necrosis) continue to be major problems and adoption of lowered steriod dosage protocols should decrease this problem. The role of HLA matching for cadaveric grafts has received renewed interest with HLA-DR typing. It is known that matching for HLA A and B antigens improves cadaveric graft survival only slightly, i.e., there is a 10-15 percent survival improvement between the best and worst grafts. In view of the logistical difficulties to obtain HLA A and B identical matches, HLA A and B typing has made little impact on cadaveric transplantation. Early series suggest that HLA-DR matching may improve cadaveric graft survival, i.e., grafts with no DR imcompatibilities show impressive survival. This effect overrides the poor survival seen in non-transfused patients in some series. If HLA-DR matching does in fact lead to improved cadaveric survival, this would have far-reaching implications for matching of HLA in cadaveric transplantation, since HLA-DR antigens are all of relatively high frequency and exhibit limited polymorphism in contrast to HLA A and B antigens. Also, it has been recognized that not all serologic positive cross-matching between donor and recipient are absolute contraindications for transplantation. Antibodies against a variety of antigens may give positive reactions with donor lymphocytes, but possibly only those against donor HLA A and B antigens will result in hyperacute rejection. The characterization of these antibodies still remains to be elucidated but it is now recognized that in certain instances, one can perform a transplant across a positive cross-match where reactivity is not directed against HLA A and B antigens.

Current Immunosuppression in Clinical Use: Azathioprine and prednisone remain the mainstay of immunosuppressive therapy. Studies now show that low steriod protocols (20 mg/day) are just as effective as higher schedules in maintaining graft survival with considerable reduction in steriod complications. Evidence that ALG is effective in improving graft survival continues to appear, albeit slowly and its remarkable effectiveness in treating graft rejection may solidify its place in the immunosuppressive armentarium in the near future. The newest immunosuppressive agent on the horizon is cyclosporin A, an antifungal agent which is extremely immunosuppressive in a number of allograft systems in a number of species. It appears to have a relatively selective effect against T lymphocytes, perhaps T helper cells and is only effective when given at the inductive phase of the immune response. In clinical use, it appears to be nephrotoxic. Although it is clearly immunosuppressive, cyclosporin treated kidneys show evidence of rejection and the apparent neophrotoxicity of the agent may be a manifestation of subclinical rejection. Other new methods of immunosuppression have been total lymphoid irradiation (see below) and thoracic duct fistula. The immunosuppressive effect of the latter modality has been known experimentally and clinically for years; the problem of prolonged drainage necessary to achieve immunosuppression are so difficult that it is doubtful the modality will gain widespread clinical usefulness. A new agent, Bredinin, is currently under study in Japan. In early studies, it has been substituted in a few patients effectively for Imuran in patients suffering Imuran-induced leukopenia and hepatitis with and without accompanying prednisone. Reports of stopping prednisone post-transplantation are becoming more frequent. In one study prednisone was discontinued in 19 of 24 HLA identical living-related donor kidney transplant recipients 1-7 years post-transplantation. One patient sustained acute rejection after stopping steriods, requiring reinstitution of steriods to reverse rejection. Eighteen of 19 patients have been maintaned off steriods 2 to 54 months (mean=18 months). Non-HLA identical living-related donor kidney recipients and cadaveric recipients have also been taken off steroids with early success with immediate positive effects of loss of excessive appetite, weight loss and lowering of blood pressure. More careful studies are required but early results suggest steriods can be eliminated in certain cases. Nevertheless, it has been shown that high dose intravenous steriods in the early post-transplant period reduced the incidence and severity of early rejection reactions. Furthermore, those that did occur could be managed with increased doses of oral prednisone. Thus, modification of the policy of use of methylprednisone may significantly improve graft survival. In diabetic recipients treated with both pancreatic and renal allografts, rejection reactions were noted to occur in both organs or the kidney only, but not the pancreas only. Cytological evaluation of in situ inflammatory responses of rejection in human renal transplantation may be correlated with severity and intensity of clinical rejection. Serial needle biopsies with assessment of various cytological parameters may have prognostic significance and permit evaluation of different immunosuppressive agents and various anti-inflammatory drugs on the in situ anti-inflammatory response. In experimental models, F(ab')2 therapy has protected rat renal allograft recipients from destruction by pre-formed antibody and prolonged graft survival. F(ab')2 fragments from presensitized dialysis patients have been prepared and given to cadaveric renal allograft recipients. A slight protective effect in treated patients was discerned, suggesting this treatment should be investigated further as a possible adjunctive immunosuppressive agent.

Complications of Clinical Transplantation (Non-Malignant): Previous cytomegalovirus (CMV) infection or reactivation of an endogenous CMV infection post-transplantation adversely affects allograft and patient survival when it occurs as the first post-transplant infection, usually in the first 3 months post-transplantation. However, persistent, recurrent or late infection apparently does not affect transplant function and patient survival. Currently, a vaccine produced against live, attentuated CMV is being tested in renal allograft recipients. The CMV disease is in progress.

Focal glomerulosclerosis (FGS) is a common histologic abnormality in long surviving clinical renal allografts, most probably secondary to chronic rejection. It is usually in the outer cortical glomeruli and frequently associated with obliterative arteriography, interstitial changes and hematuria. FGS in the early post-transplant period can also represent occurrence of the original disease. Percutaneous transluminal dilatation (PDT) of renal transplant arterial stenosis for relief of renal transplant induced hypertension has been shown to be effective. Use of PDT can thus avoid the very difficult and hazardous (to the kidney) surgical repair of the renal artery stenosis. PDT should precede surgery as the therapeutic procedure. Coronary angiography is a safe procedure to investigate coronary disease in dialysis and transplant patients. Coronary disease accounts for 65 percent of deaths in such patients with 75 percent occlusion of one vessel, but left ventricular dysfunction correlated better with overall mortality. Renal transplantation may be performed more safely in older patients or diabetic patients studied by coronary angiography and such patients can be treated with by-pass surgery prior to transplantation.

Complications of Clinical Transplantation (Malignant): Studies of malignant disease in patients in Europe with end-stage renal disease treated by dialysis and transplantation have confirmed the higher incidence of malignancy in transplanted patients, but have failed to support the contention that malignancies occur more frequently than expected in chronic non-transplanted patients. However, in Australia, skin and other cancers in cadaveric recipients is now a major cause of morbidity and mortality following otherwise successful cadaver renal transplantation. The incidence of cancer of all types in patients surviving 1, 5 and 10 years after transplantation was 26, 43 and 47 percent respectively.

Many types of malignancy have been observed in transplant recipients. The incidence of these de novo malignancies range from 2 percent to 13 percent in several large series, numbering from 503 to 1,016 patients. Until May 1980 the Denver Tumor Registry has received data concerning 1,081 types of neoplasms that developed in 1,023 patients of whom 1,002 received kidneys, 18 hearts, 2 livers and 1 bone marrow transplants. Solid lymphomas made up 207 of the cancers. If we exclude non-melanoma skin cancers and in situ cancers of the cervix of the uterus, which are excluded from most cancer statistics, the lymphomas made up 29 percent of the neoplasms. This is in sharp contrast with an incidence of 3-4 percent in the general population. Lymphomas constitute a very important post-transplant malignancy. A recent update of the Denver Tumor Registry showed that there were 207 lymphomas in 206 patients (one had a reticulum cell sarcoma and a Kaposi's sarcoma). The distribution of the tumors was as follows: reticulum cell sarcoma (114 patients), Kaposi's sarcoma (35), miscellaneous lymphomas (28), lymphosarcoma (12), atypical lymphoma (6), plasma cell lymphoma (4), Hodgkin's disease (1). A striking feature is the rarity of Hodgkin's disease (2 percent), which makes up 34 percent of lymphomas in the general population. Non-Hodgkin's lymphoma is 45-100 times more common in transplant recipients than in the general population. Fifty-five percent is made up of a large cell lymphoma. The cells comprising these tumors closely resemble activated lymphocytes. Several lymphocytes have been studied by modern immunologic techniques and have been found to consist of B lymphocytes. The tumors occurred in a relatively young age group. The average age at the time of transplantation was 38 (range 5-70) years. The lymphomas appeared at intervals ranging from 1 to 146 (average 28) months after transplantation. Excluding 35 patients with Kaposi's sarcoma, the remaining 172 recipients were divided into 91 (53 percent) with localized lesions and 81 (47 percent) with regional or widespread lesions. In the latter group, the distribution of the lesions resembled that seen in the general population. Unusual features were 19 percent involvement of the central nervous system and 33 percent involvement of the renal homograft. Of the patients with localized lymphomas, 60 percent had lesions in the central nervous system, but the liver, spleen, lymph nodes, or bone marrow were rarely involved. In the overall series of 172 patients, 42 percent had central nervous system involvement, whereas such involvement occurs in less than 2 percent of lymphomas in the general population. The brain was affected in 76 percent of the transplant recipients.

Kaposi's sarcoma is surprisingly common in transplant patients. In the general population it makes up 0.6 percent of all malignancies but comprises 4.8 in organ transplant recipients (if we exclude nonmelanoma skin cancers and in situ carcinomas of the uterine cervix). Sixty percent of the patients had involvement of the skin or the otopharyngolaryngeal mucosa or both. The remainder had visceral involvement, particularly of the gastrointestinal tract or respiratory system. Most patients with visceral involvement failed to respond to treatment. Five of 21 (24 percent) patients with nonvisceral lesions had complete or partial remissions following cessation or reduction of immunosuppressive therapy, suggesting that the changes in therapy may have played a role in causing tumor regression.

Studies by several workers using immunoperoxidase and cell marker techniques suggest that a few of the lesions are polyclonal in origin. They may represent a proliferative phase of poorly differentiated lymphoid cells midway in development between a possibly virus-induced polyclonal lymphoproliferative process and a monoclonal lymphoma. These findings have therapeutic implications. Such "lymphomas" should not be treated with cancer chemotherapy but by reduction of the immunosuppression. Thus far, the origins of seven lymphomas in transplant patients have been identified, either by the use of sex chromatin markers (where donor and recipient were of different sexes), or by HLA typing of the donor and recipient and the lymphoma cells. Six tumors were of host origin and one arose from donor cells. The mortality from non-Hodgkin's lymphoma in transplant recipients is 48 times greater than that observed in the general population. Only 22 percent of the 206 patients in this series are currently alive, although it must be conceded that not all the recipients died from their malignancies. Of the patients with non-Kaposi lymphomas, only 15 percent are alive, whereas 51 percent of patients with Kaposi's sarcoma are still living, mostly those with nonvisceral lesions. These tumors probably arise from a complex interplay of chronic antigenic stimulation, disturbances of immunity (either preexisting or acquired after transplantation), the immunosuppressive drugs, and oncogenic viruses.

Organ Procurement: Some progress has been made in acceptance of the concept of cadaveric organ donation, although organs for clinical transplantation remain in short supply. The concept that irreversible cessation of total brain function can be equated with the death of a person continues to be consistent with medical and scientific evidence and this concept has gained considerable legal and social acceptance throughout the civilized world. Seven states have enacted statutory definitions of death in the last three years. This brings the total to 25. In two countries, Canada and Australia, the legality of brain death pronouncements is recognized in some provinces and states but not in others. In 10 other countries or commonwealths, brain death is recognized legally. These are Argentina, Austria, Czechoslovakia, Finland, France, Greece, italy, Norway, Puerto Rico and Spain. In Great Britain, brain death pronouncements are recognized in the code of Practice which has quasilegal status. In Belgium, Germany, India, Ireland, New Zealand, South Africa and Switzerland, brain death is accepted and utilized medically although there is no specific legal recognition given to such pronouncements. In addition to the more widespread statutory and judicial recognition afforded brain death pronouncements over the past several years, several other recent developments indicate that still wider legal recognition is likely. The first is the adoption in August 1978 of a model Uniform Death Act by the National Conference of Commissioners on Uniform State Laws in the U.S. A second important development has been a change in the position of the A.M.A. away from opposition to statutory definitions of death. A third recent development has been the recognition by some members of the Right-to-Life and the Pro-Life movements that statutory definitions of death and so-called "right-to-die" laws, or laws that permit euthanasia, deal with quite different issues.

Clinical Immunosuppression

A. Antilymphocyte Antibodies in Clinical Transplantation

After many years of intermittent clinical testing, there is now very strong evidence that antilymphocyte antibodies (ALG) in various preparations are highly immunosuppressive and of benefit in clinical organ transplantation. The Massachusetts General Hospital group presented considerable evidence that ALG given prophylactically is effective in augmenting first cadaveric graft survival at one year. This improved survival was also accompanied by decreased frequency of rejection reactions, improved renal function (for a given steriod dose), reduced median steriod doses required and decreased hospitalizations in the ALG group. Similar results were reported by the Minnesota group using antilymphoblast globulin. Furthermore, diabetic results were reported by several groups (Columbia, Minneapolis, Washington and Indianapolis) identifying that ALG is extremely effective in treating acute renal allograft rejection. ALG reversed rejection which could not be reversed by standard steriod treatment. Indeed, the place of ALG in the immunosuppressive armentarium may be that of the best agent for the treatment of rejection. The problems of potency and standardization still plague the clinical use of ALG. An encouraging report was the possibility that xenogeneic monoclonal antibodies to human T cell subpopulations to standard, high-potency preparations for clinical use.

B. Pharmacologic Immunosuppression

Steriods: The complications steroids produce have become depressingly familiar to most transplant centers. Heavy steroid dosage during the first month after transplantation is probably not required. Over the last decade the best results of cadaveric renal transplantation in Great Britain have come from the Belfast Unit. The patients receive just 20 mg of prednisone daily from the day of transplantation although four doses of hydrocortisone (200 mg) are given during the first 18 hours. Other centers have been slow to adopt a low-dose steroid policy although opinions may change now that a controlled trial has been carried out (Oxford group). Graft survival was identical in the two groups (60 percent surviving at six months), and rejections in the low dose group were no more frequent or severe. There were more steroid complications in the high dose group, including the three deaths in this group. The need for high doses of steroids on the day of transplantation has been challanged by the Milwaukee group. The need to give steroids indefinitely has been questions by sporadic reports that patients whose immunosuppression has been stopped can continue to enjoy normal kidney function. It has been most people's experience, however, that steroids cannot be discontinued. Nevertheless, at least two reports identified the fact that steroids can be stopped (Imuran continued) in HLA-matched recipients and to a lesser extent in cadaver recipients.

Cyclophosphamide: Cyclophosphamide has never found a secure place in clinical transplantation. There is some evidence from rabbit experiments that the triple drug regimen of cyclophosphamide, azathioprine and prednisone prolongs kidney transplant survival more effectively. However, two controlled clinical trials have recently demonstrated no advantage for those patients who have received all three drugs, rejection being just as frequent with triple as opposed to double drug therapy.

Imidazoles: The imidazoles and related compounds have a variety of properties (e.g. antifungal) but recently some have shown to be immunosuppressive as well. The group in Wales carried out a controlled clinical trial in which niridazole had been given in addition to azathioprine and prednisone to patients receiving their first cadaver kidney transplant. In this two-center trial, graft and patient survival was not improved by niridazole although in one center the one year graft survival rate improved from 48 percent in the control group to 62 percent in the group taking niridazole. Bredinin is another imidazole compound that has been used both experimentally and clinically to prolong kidney survival.

Management of Rejection Episodes: Although ALG and perhaps cyclosporin-A may be effective in reversing rejection, large doses of steroids are usually required in clinical transplantation. For some years the 1 gm. i.v. bolus of methylprednisolone has been popular treatment, although controlled clinical trials have shown this to be no more effective than much lower doses of steroids given orally or i.v. Other compounds have been given with steroids at times of rejection but probably contribute little to graft outcome. Thus actinomycin-C and cyclophosphamide are rarely given nowadays. Transplant survival was not improved with addition of heparin to rejection treatment and when heparin was given intravenously, severe bleeding occasionally occurred.

C. Total Lymphoid Irradiation

At most transplant centers, 30-50 percent of recipients or renal allografts from cadaver or HLA nonidentical related donors irreversibly reject the graft within two years. Patients who rapidly reject a first graft usually do the same after a second graft. These results are a stimulus to test alternative immunosuppressive protocols. At the University of Minnesota, they have evaluated TLI for its ability to affect kidney allograft survival in dogs either with or without the administration of donor bone marrow. In 9-10 dogs with technically-successful transplants, renal allograft survival was prolonged, and in 2 of 6 recipients given donor bone marrow, the kidney grafts functioned for more than one year without adjunctive immunosuppression. On the basis of these results, the Minnesota group initiated a clinical trial of TLI. So far, 15 uremic patients at high risk for rejection of a renal allograft (14 recipients of secondary or tertiary grafts and 1 recipient of a 2 haplotype-mismatched primary graft) have been treated with total lymphoid irradiation before transplantation. One graft never functioned after transplantation and was a technical failure. One was rejected at three weeks after cessation of immunosuppression because of gastrointestinal bleeding. One patient died at 5.5 months of a lymphoma. The other 12 grafts have functioned for 1 to 16 months.

Patient Selection: Two catagories of patients have been selected for a clinical trial of TLI and kidney transplantation at the University of Minnesota. The first category includes those patients who previously rejected a renal allograft. The second category of patients accepted for total lymphoid irradiation are those patients who will receive a primary renal allograft from a distant relative or a 2 haplotype mismatched sibling--a subcategory where the results of transplantation are not as good as for those patients who received mismatched (one haplotype) grafts from closely related donors.

Irradiation: The patients received 100-125 rads at each dose and no more than 5 doses/week. The total dose delivered to the 15 patients ranged from 2500 to 4050 rads. The TLI was administered over a period ranging from 24 to 124 days, and the interval between completion of TLI and transplantation ranged from 1 to 222 days.

Splenectomy: All patients were splenectomized.

Bone Marrow Adminstration: Four of the patients received low dose bone marrow (0.5x108 nucleated cells/kg) from their donor at the time of transplantation. A low dose was used to reduce the risk of graft versus host disease.

Pharmacologic Immunosuppression: All the patients received maintenance azathioprine (adjusted for WBC count) and prednisone after the transplant, but antilymphocyte globulin was not administered in the immediate post transplant period. Thus, there were really two protocols: (1) TLI plus pharmacologic immunosuppression and (2) TLI plus donor bone marrow plus pharmacologic immunosuppression.

Complications: Leukopenia requiring interruption of TLI occurred in most of the patients. Serious complications occurred in five patients, although they were not all necessarily related to TLI. These included pneumonia, candida esophagitis, upper gastrointestinal bleeding, and two cases of lymphoma, one fatal.

Rejection Episodes: Rejection episodes have occurred in five patients (nos. 1, 2, 9, 10 and 13). They were reversible in four patients.

Immunological Monitoring: Total lymphoid irradiation had a profound effect on immune functions in most of the patients. The absolute T-cell levels fell 10-20 percent of pre-TLI levels. The mixed lymphocyte culture (MLC) response to a pooled allogeneic stimulus fell to less than 10 percent of the pre-TLI response. The response to con-A and phytohemagglutinin was 10-15 percent of controls. The first 800 rads of TLI had the most profound effect and by 1600 rads all patients except one (no. 13) had low immunologic responsiveness on in vivo testing. These changes persisted for at least six months after transplantation.

Test for Chimerism in Bone Marrow Recipients: Tests for chimerism in the four recipients of bone marrow have been inconclusive.

Graft and Patient Survival: The one patient treated with TLI who received primary renal allograft and bone marrow from a 2 haplotype mismatch sibling currently has a functioning graft at 10 months with no rejection of a previous graft; there was one technical failure, one death with a functioning graft at 5.5 months, and one loss from rejection. The other eleven patients have functioning grafts at 1, 1, 3, 3, 5, 6, 10, 12, 12, 14 and 16 months.

Conclusions: The Minnesota group has applied lymphoid irradiation to a group of patients that they consider at high risk for rejection if treated by conventional immunosuppression alone. The graft survival rates in this group of patients have been remarkably good and it is apparent that total lymphoid irradiation is an effective adjunct for immunosuppression in renal allograft recipients. They have used TLI primarily for its generalized immunosuppressive effect, although an attempt was made to induce specific immunologic responsiveness to the donor in four patients by administration of donor bone marrow. It may be that larger doses of bone marrow will be necessary for chimerism or tolerance induction, but this may also increase the incidence of graft-versus-host disease. At this point, they envision total lymphoid irradiation as being most useful for its general ability to depress immune responsiveness. TLI allows transplantation to be carried out with a good success rate in the highly immunoreactive individual. Whether the indications can be broadened in the future remains to be seen. The occurrence of post-transplant lymphoma in two patients is disturbing, but they do not think that total lymphoid irradiation can be directly implicated. The occurrence of lymphoma may be related to the profound immunosuppression induced by the combination of TLI and pharmacologic immunosuppression. First, the immunologic monitoring data suggests that the dose of TLI administered was more than required. Immunologic responsiveness was profoundly depressed after 1600 rads. Recovery will occur over time, as seen in the two patients who had a long interval between the TLI and transplant, but if pharmacologic immunosuppression is administered, the depression of the immunologic responsiveness persists. Second, total lymphoid irradiation can be administered to the mantle and inverted Y-field simultaneously, but leukopenia and gastrointestinal symptoms can appear. On the basis of this experience, their current plan is to administer 2000-2500 rads of TLI. The final dose administered will depend on the results of immunologic monitoring. If all parameters are depressed by 2000 rads, radiation will be stopped. If recovery begins to occur before transplantation can be accomplished, additional radiation will be given, but not to exceed a limit of 2500 rads. In conclusion, the current clinical experience suggests that TLI plus pharmacologic immunosuppression prevents graft rejection better than conventional immunosuppression alone.

D. Cyclosporin-A (CY-A)

Experimental Status: The mechanism of action of CY-A still remains largely unknown. It has been shown that formation of cytotoxic effector lymphocytes is highly sensitive to CY-A. Several reports indicate that rejection can be overcome with CY-A. Provided the compound has previously been administered, i.e., used preventively and then stopped, a delayed onset or a relapse may be effectively reversed if CY-A treatment is resumed. This holds true for many models and species. GVHD can not only be prevented but also reversed and kept suppressed when treatment is continued. Upon cessation of therapy most animals will eventually relapse into a GVHD. These findings with bone marrow grafted rats do not correlate with the clinical results, where therapeutic treatment alone of acute GVHD failed. The question whether CY-A induces tolerance has been repeatedly asked. The answer is both yes and no, depending on the model and species used. A prolonged state of possibly specific tolerance seems to be achieved in rats and rabbits receiving organ allografts concomitantly with 2-3 weeks prophylactic treatment of CY-A. Similarly, when prophylactic treatment of human bone marrow recipients was ceased after five months, only one out of 12 patients developed a GVHD. However, skin allografts in mice and dogs will only survive as long as CY-A is administered, thus indicating that tolerance is not established. This also appears to apply to the majority of other models in several species. One should remember that the action of CY-A is fully and rapidly reversible, as demonstrated in long-term toxicity studies. Since the effect of CY-A is reversible both in vivo and in vitro, it appears that suppressinis not achieved through elimination of certain lymphocytic clones but rather by their repression. There is evidence that priming occurs in the primary response under CY-A treatment, despite the fact that no significant response can be measured, because a later antigenic challenge will elicit a genuine secondary response. Therefore, antigen recognition seems not to be affected. How does CY-A affect the immunocompetent cells? There is much evidence today that CY-A does not affect precursor cells (hemopoletic stem cells), and resting or dividing lymphocytes. Nor does it seem to interact with macrophage functions. It affects mainly T cells, although a restricted effect on B cells has been demonstrated. The sensitive phases are the early cellular events in response to mitogenic triggering, possibly also cell to cell interactions, including lymphokin production and release. It appears furthermore that some functional subsets of lymphocytes are preferentially inhibited in comparison to others, e.g., primary T-helper cells and formation of cytolytic effector cells are suppressed by CY-A, whereas T-suppressor cells are not. Another approach to investigate the mechanism of action of CY-A consisted of using flow cytophotometry to assess distribution analysis of cellular DNA content. A dose-dependent inhibition of Con-A stimulation of mouse spleen cells by CS-A was found between 24 and 72 hours of incubation. DNA distribution patterns revealed that the majority of cells were arrested in the G0 and G1 phases of the cell cycle. Similarly, CY-A-arrested proliferation of CY-A sensitive 1-lymphoid cell lines in the G1 phase, whereas cycling of the CY-A resistant lines was not detectably affected. In conclusion, CY-A can be considered as the prototype of new generation of immunosuppressive agents. By its specific action on defined lymphocytic functions, it may further prove useful in unravelling basic immunological mechanisms.

Clinical Studies: Cyclosporin-A is being used at several centers around the world in clinical trials. The experiences of the Canbridge and Denver groups are most extensive. There is no doubt that CY-A is highly immunosuppressive in man for clinical kidney transplantation. Patients given CY-A have tolerated cadaveric grafts without adjuvant steroid therapy. Early results are extremely encouraging. Certain problems have arisen. These include (1) CY-A may be nephrotoxic, (2) in those patients who reject on CY-A, the addition of conventional immunosuppressive drugs (steroids, Imuran) has been associated with a high incidence of serious infection, and (3) there may be a higher risk of lymphoma induction in patients on high doses of CY-A.

Clearly, extensive, controlled clinical trials are required to further evaluate and identify the final role of CY-A in clinical organ transplantation.

E. Blood Transfusions

Numerous retrospective studies have confirmed the clinical observation that blood transfusions given prior to transplantation improve the survival of cadaveric kidney transplants. Several prospective studies in progress appear to confirm this improved survival. A dose effect is probably operative in that there is a progressive improvement in cadaveric graft survival from 0 to 20 transfusions, i.e., no transfusion had a 38 percent one year survival and 20 transfusions had a 72 percent survival. In contrast to previous thoughts, frozen blood (leucocyte-free) is essentially ineffective compared to other types of transfusions. A prospective study testing leucocyte-poor versus leucocyte-free blood showed the efficiency of leucocyte-poor and the inefficiency of leucocyte-free blood. The effect of transfusions at the time of transplantation continues to be debated, but peritransplant transfusions are probably not critical in that the transfusion effect was discerned up to one year post-transfusion. The duration of dialysis was not important in obtaining the transfusion effect, i.e., no matter how long patients are dialyzed, they do poorly as a group if not considered pre-transplantation. With respect to blood transfusions and HLA matching, the effect of matching was out-weighed by blood transfusions. It is now believed that over greater than 90 percent lymphocytotoxic antibodies to a normal panel decreases cadaveric survival; only 4 percent of recipients given more than five blood transfusions are 90 percent sensitized and this increases to 7 percent after 10 and 12 percent after 20 transfusions. Recipients of living-related kidneys given non-specific pretransplant blood transfusions showed improved survival, but to a less extent than with cadaveric donors. However, the use of donor specific blood in recipients of living related kidneys may assume great importance. It is known that recipients of one-haplotype mismatched living-related kidneys with high mixed lymphocyte culture reactivities have failure rates equal to cadaveric recipients. Administration of donor-specific blood transfusions prior to proposed transplantation results in donor-specific antibodies which precludes transplantation in about 30 percent of those so-transfused. The remaining non-responding recipients can be transplanted and have a greater than 90 percent success when transplanted with their specific donor. It is not clear that this is an enhancing effect of donor specific blood or donor selection. More studies are needed in this important area. These initial studies performed by the San Francisco group clearly show that donor-specific blood transfusions may be a significant step forward in the management of HLA mismatched living-related donor recipient transplant pairs.

THE MAJOR HISTOCOMPATIBILITY COMPLEX

A. MHC in General Biologic Recognition: Its Theoretical Implications in Transplantation

Today, the MHC appears schematically bipolar, which is probably the consequence of several duplications and mutations originating from two primitive genes. Both classes of molecules possess a common feature. They seem to serve as a password between two cells of a being that recognize each other as belonging to the same organism and thus are able to cooperate, apparently thanks to their identity at the level of either class I or II gene products. Thus, one of the functions, or maybe the genuine function, of the MHC progressively emerges and seems to be self-recognition. The two classes of molecules have a common function. They might serve as recognition signals between cells of the same organisms--signals necessary, but probably not sufficient, to allow the effective cooperation between two subsets of cells. The most striking feature of this recognition system is the apparent need of identity at one of the two classes of MHC molecules. This MHC restriction of self-recognition has been essentially demonstrated as occurring at the various steps of the immune response between cells with immunocompetency. This is the case in T effector cells of an antivirus, antichemical, or anti-H minor type; these cells only act (with rare exceptions) if the target cell bearing the viral, chemical, or H minor antigen share with the thymic epithelium, which has selected the effector cells, at least one of the class I products.

The mechanisms underlying this process of self-recognition are still unknown. This process of self-recognition could appear irrelevant to transplantation where only allorecognition seems to occur. This view is misleading for at least two reasons. First, the rejection process is triggered by the first step of non-self-recognition, which takes place during the first hours of the transplantation. The role of HLA-D incompatibilities in non-self-recognition is essential. The selection of the donor, either by negative MLR for related donors or by HLA-DR matching (with, in most of the cases, a consecutive HLA-D matching) for unrelated donors, avoids the activation of the corresponding clones of T helper cells. It has been observed by several teams that two DR identities allow a better survival while there is no difference between one or zero DR identities. It seems that a unique D/DR incompatibility was enough to allow non-self-recognition and trigger the rejection process. It would be logical, if the conclusion is correct, to try to achieve as often as ossible two DR compatibilities in preference to HLA-A, B, C, at least when the recipient is a nonresponder. If the recipient has developed antibodies after transfusion (responder), the T helper cells are likely to be already present and the effect of D/DR identity should be less. The priority in this case is for HLA-A, B identity. Secondly, the self-recognition system must be at work for the development of unresponsiveness, or at least for the inhibition of the non-self-recognition. This is suggested by the presence of suppressor cells after secondary or tertiary MLC. These suppressor cells act in feedback on their own responding cells, thanks to a suppressor soluble factor detected in the supernatant of the culture. It has been shown that this factor is produced by hyperimmunization in vitro against DR incompatibility(ies). Added to a primary MLR, it is able to suppress the proliferative response of the responding cell, whatever the DR specificity of the stimulating cell. Moreover, it suppresses the autologous responding cell but also some other. Thus, the suppressor factor is not DR specific, although produced by reacting against a DR incompatibility, and is restricted to some responding cells, principally the autologous responding cells. Thus, feedback is possible only by self-recognition, probably between two subsets of T cells: the one that secretes and another that accepts the factor. A provocative proposition would be to systematically treat future recipients by immune suppression during the transfusion period in order to avoid this helper predominance. Of course this schema is, for the time being, purely speculative but it corresponds to the present stage of knowledge and also is fully compatible with the data presently available in man as well as in monkey. In conclusion: (1) the main function of the MHC products could be the self-recognition between all the body cells for the class I molecules and between the immunocompetent cells for the class II molecules; and (2) self-recognition is fundamental in transplantation according to the feedback unresponsiveness of T responder cells. This process could be one explanation for the beneficial effect of transfusion in transplantation.

B. HLA and Disease Associations with Special Reference to Mechanisms

An impressive variety of diseases are now known to be associated with various HLA factors, and this information has considerable impact on our concepts of disease heterogeneity and adds very significantly to our knowledge of the inheritance of disease susceptibility. Apart from C2 deficiency and 21-OH deficiency, the mechanisms behind the HLA associates are largely unknown. In fact, we do not know whether the HLA factors now known to be associted with the diseases are casually involved or whether they are merely markers for as yet unknown factors occurring in linkage disequilibrium with the known ones. In addition, A, B, C, and D/DR antigens, the HLA system also controls some components of the complement cascade: properdin factor Bf of the alternative and the second (C2) and fourth (C4) component of the classical activation pathway. It may be worth noting that both the loci for HLA-controlled complement factors and that for 21-OH deficiency have been mapped close to the HLA-B locus. It seems reasonable to assume that the pathogenesis in disorders "primarily" associated with HLA-D/DR antigens involve inadequate action of Ir or Is determinants, some of which may be the D/DR antigens themselves. Diseases "primarily" associated with HLA-A, B, C factors may involve preferential restriction phenomena or molecular mimicry. However, both HLA-D/DR, B, and C associated disorders could also involve as yet unknown variants of HLA-controlled complement components. Celiac disease and perhaps dermatitis herpetiformis may represent involvement of an Ir determinant with specificity for a component in gluten, hypersensitivity to which causes celiac disease. An HLA-DR3-associated Ir gene could also be involved in most, if not all, of the other DR3-associated disorders in which autoimmune antibodies are found. One problem here is that quite a number of different autoantibodies are involved, and if it is only one Ir determinant that is resonsible for all the associations, it must be postulated that it has a rather broad specificity. It is perhaps more plausible that the hypothetical Ir determinant has a more basic, general role for certain immune responses, or that there is a cluster of DR3-associated Ir determinants with specificities towards various organs. Preferential HLA-A, B, C restriction in T-lymphocyte-mediated lysis of virus-infected or hapten-conjugated cells might explain the associations between HLA-B35 and subacute thyroiditis and between HLA-B5 and Behcet's disease. At the time of this writing, the mechanisms discussed above (i.e., Ir and/or Is determinant involvement, preferential A, B, C restriction, complement variation) are considered the best candidates for most of the presently known HLA and disease associations. However, these mechanisms are unlikely to be involved in idiopathic hemochromatosis or 21-OH deficiency. It has also been suggested that some HLA factors may serve as receptors for virus, but there is not much evidence supporting this assumption. Finally, the HLA-D/DR antigens are differentiation antigens, and it may be speculated that other HLA antigens may control other cellular interactions that could lead to associations between HLA and various diseases.

C. Factors Influencing Kidney Graft Survival

Many factors influence the outcome of a clinical allograft. As far as the HLA-A and B antigens are concerned, some groups claim that they can find a 40 percent difference between unrelated HLA-A and B identical and HLA mismatched grafts, while others find only a difference of 10 percent or 15 percent. In a collaborative analysis between Eurotransplant and the European Dialysis and Transplantation Associates, a clear-cut and quite significant influence of HLA-A and B matching on patient survival was found. It is logical to assume that this is due to the large amount of immunosuppression that must be given if the donor and recipient are severely mismatched for the HL-A and B antigens. There is general agreement that blood transfusions should be given, but more study is needed to determine whether the transfusion should be given pre- or pertransplantation and the optimal number of transfusions needed. As far as HLA-DR is concerned, the only real agreement is that more data are needed. The majority of the published studies show a clear-cut effect of HLA-DR matching, but the data collected during the Eighth Histocompatibility Workshop were not convincing. The question arises whether if one matches the HLA-DR one can "forget" about HLA-A and B matching. Some graft survival data indicate that the effect of HLA-DR matching is potentiated by HLA-A and B matching. In the HLA-DR-identical group, graft survival is near 90 percent one year post-transplantation if donor and recipient are also HLA-A and B matched or mismatched for only one antigen. On the other hand, HLA-DR matching and blood transfusions do not potentiate each other, or to a far less extent. However, some of the kidney grafts that are HLA-A and B matched and/or HLA-DR matched are rejected in the first 2 months after transplantation. This might indicate that factors outside HLA influence graft survival as well. It could be proven that the same antigen that is present in the endothelium is also present on monocytes. In other words, the endothelium and the monocytes share alloantigens that can be recognized on the endothelium by immunofluorescence and on the monocytes by complement-dependent cytotoxicity. These endothelium-monocyte (EM) antibodies are formed especially in kidney graft recipients that are HLA-DRw6 positive. Also, the distribution of the EM and other alloantigens in kidney tissue has been investigated. The HLA-A and B or HLA-Bw4 or Bw6 or the HLA-DR antigens could not be demonstrated in reproducible fashion in renal tissue. The HLA-B7 antigen is perhaps an exception. In contrast, the monomorphic monoclonal antibody against the HLA-A, B, C molecules and against HLA-DR molecules was strongly positive. The ABO antigens are present on the endothelium of arteries, arterioles and peritubular capillaries. These findings raise more questions than they answer. In the first place, it is difficult to find a correlation between matching the HLA-A and B and HLA-DR if these antigens are not present in kidney tissue. The fact that more potent monoclonal monomorphic antibodies were positive could be in agreement with such an assumption. The finding that the LB or MB antigens could be easily demonstrated on kidney tissue seems to lend support to the findings that matching for these antigens improves graft survival. All this emphasizes the important role EM antigens might have as targets in graft rejection. There is evidence for a role of host factors in graft survival. Patients with positive skin tests for microbial antigens were studied and one could show that those patients who had positive skin tests had first rejection crises which were on the average, on day 4, and thus a lot earlier than those who had negative skin tests. More recently, skin tests with DNCB in a quantitative manner have been performed on transplant recipients. Seventy percent of grafts with a DNCB score of less than 3 were still functioning after six months, while those that had a DNCB score of greater than 3 had a graft survival of 11 percent only. Fifty-five patients were studied for CML reactivity and about two-thirds of them became CML-nonresponsive to the specific kidney donor. This CML nonreactivity is donor-specific because the lymphocytes of the recipient, when tested against the lymphocytes of an unrelated donor in the CML test, gave a positive reaction. It turned out that CML nonreactivity coincides in a significant manner with good renal function. Recipients of male grafts and those that were HLA-B compatible had the best chance to become CML nonreactive against their donor. It was of further interest that recipients who were DR4-positive appear to be especially prone to develop CML nonreactivity. This might be an indication that the occurrence of CML nonreactivity is also under Ir gene control. In summary, it is felt that the most important factor in the determination of graft survival might be the responsiveness of the graft recipient. If the recipient is a low responder, neither matching for DR, blood transfusion, or matching for the HLA-A or B or EM antigens is necessary. However, if the recipient is a responder, these factors become important.

IMMUNOBIOLOGY--MECHANISMS OF ALLOGRAFT REJECTION

The mechanisms of allograft rejection have been investigated by various techniques. Several observations have been made using a sponge matrix graft in an animal model in place of a skin graft, so that cells infiltrating the graft can be studied. It was reported that an immunologic specific interaction takes place between sensitized cytotoxic lymphocytes and the graft antigen, which appears to result in the recruitment of unsensitized lymphocytes to the rejecting graft and the recruitment of more sensitized lymphocytes from the circulation. There appears to be a population of precytotoxic lymphocytes which are particularly motile and appear early in sensitization. These lymphocytes migrate to the graft in response to chemotactic factors present in the graft where cytotoxic maturation takes place. A full complement of cytotoxic cells can develop in the graft from proliferation of these precytotoxic lymphocytes without further contribution from the host. Electron microscopic studies have contributed information on the mechanism of action of cytotoxic lymphocytes. These cells produce cytoplasmic projections which penetrate into the target cell and bind the lymphocyte and target cell, but do not appear to induce lysis. A re-examination of the role of passenger lymphocytes in the rejection of skin allografts suggests that these cells do not contribute to the immunogenicity of the graft, in contrast to earlier evidence. An examination of the role of skin specific alloantigens in graft rejection has been done. Using epidermal cells as stimulators and targets of cell-mediated cytoxicity, it has been shown that there are alloantigens unique to epidermal cells. These non-MHC antigens are not shared by haploididentical lymphocytes and are capable of evoking strong cytoxic responses. The presence of these antigens may explain the immunogenicity of MHC compatible skin allografts and the differences observed in the survival of skin allografts from that of kidney and heart allografts.

Experiments involving the study of corneal allografts have examined the mechanisms which makes the cornea a privileged graft site. It was concluded that access of host immunocompetent cells to the graft is required for corneal allografts to reject and that this access is facilitated by the presence of an inflammatory response or blood vessels in the graft bed. Presensitization of the graft recipient to donor antigen did not affect the survival time of corneal grafts in normal (i.e., non-inflamed, non-vascularized) graft sites.

Several investigators are studying the influence of non-HLA antigens on grafts other than skin. Experiments with rat kidneys and hearts which have been disaggregated into single cell suspensions demonstrate differences in antigentic expression, immunogenicity and immunosensitivity of different allograft components. Antigens on the vascular endothelial cell (VEC) appear to have an important role in renal allograft rejection. These antigens are not on lymphocytes or renal cells, but are present on monocytes. Antibody to VEC antigens appear to have a higher correlation with kidney graft rejection than antibody to lymphocyte antigens. VEC have been used to replace macrophages in vitro studies of the proliferative responses to T cells and it has been shown that these cells are as capable as macrophages in presenting antigen to T cells in an immunogenic form.

The classic theory that hyperacute rejection is caused by preformed humoral antibody has been questioned by experiments in rabbits and dogs. Presensitization of the host to the graft donor was more accurately predicted by antibody dependent cellular cytoxocity tests than by testing humoral antibody to lymphocyte antigens. This suggests that hyperacute rejection is associated with cell-mediated immunity.

Both specific and non-specific methods to modify the immune response are being studied and the mechanisms involved in the induction of unresponsiveness are being elucidated. It was reported that there are genetic influences on the mechanisms involved in neonatal tolerance. A study of the reactivity of lymphoid cells from mice made tolerant as neonated across the K or I or I and D regions of the H-2 complex suggest that K region alloantigens induce tolerance via clonal deletion while I region differences evoke a suppressor mechanism. Adult mice and monkeys have been made specifically unresponsive to skin allografts by the use of antilymphocyte serum (ALS) and donor bone marrow. Lymphocytes from unresponsive mice are unable to show direct anti-donor cytotoxicity and exhibit low proliferative responses in mixed lymphocyte reactions against the donor, but can differentiate into cytotoxic cells when resensitized. This indicates that cells sensitized to skin donor antigens are present in mice bearing enhanced skin grafts, but that the effector activity of these cells are blocked in some way. Many reports suggest that suppressor cells are one of the principal mechanisms of suppression in both specific and non-specific unresponsiveness. Mice grafted after treatment with ALS and procarbazine hydrochloride have evidence of suppressor cells in their spleens. Preoperative treatment with a single dose of 1-5 1 of blood increased the proportion of unresponsive mice and suppressor cells were found in the spleens and lymph nodes. Both donor-specific blocking factors and suppressor cells were found in rats bearing long-term cardiac allografts after treatment with ALS and Palladium-109-hematoporphyrin. Donor specific suppressor cells were also found in the spleens of rats bearing long-term cardiac allografts after pretreatment with donor-specific blood.

The use of blood transfusions and blood products as a method of inducing unresponsiveness has been studied in several animal models. Dogs treated with a short course of ALS and injected with donor platelets post-transplantation showed significant prolongation of kidney allografts. Skin allografts on ALS treated mice can be significantly prolonged by donor specific and non-specific blood transfusions given before grafting. An optimal interval exists between blood transfusion and grafting to achieve a positive effect and this interval varies depending on whether the blood is donor-specific or non-specific. In experiments using congenic mice transfusion of donor specific blood had no effect on prolonging cardiac allografts while non-specific blood induced significant prolongation.

In the field of HLA-D typing, several investigators have studied the relationship between HLA-D antigens typed by primed lymphocyte typing (PLT) and by serological methods. There is evidence that the determinants typed by these two methods are the same, while differences between these determinants could be seen in MLC. Studies of the expression of HLA-D antigens on various tissues were done using monoclonal antibodies. It was concluded that HLA-DR antigens have a wide tissue distribution (gastrointestinal, kidney, lungs) and their presence on renal endothelial cells may account for the association of kidney allograft rejections with sensitization to DR antigens. Several new assays were described to achieve rapid typing for HLA antigens. An assay has been developed for the T lymphocyte insulin receptor which becomes positive during mixed lymphocyte response. It was shown that responder lymphocytes developed an insulin receptor after stimulation with cells mismatched specifically for the HLA-D region. It was suggested that this could be useful as a rapid method of HLA-D typing. Another rapid assay was described involving the determination of intracellular ATP for evaluating complement dependent cytotoxicity mediated by anti-HLA antibodies. The measurement of loss of ATP in antibody coated target cells was as sensitive an indicator of cell injury as 51Cr release and HLA typing by this method correlated with typing results achieved by standard techniques.

In tumor immunology, studies have focused on natural killer cells and the influence of genetics on tumor growth. Three categories of natural killer cells have been defined - those reactive against lymphomas and those reactive against non-lymphomas, as well as a third category which are generated in culture. Natural killer cells have been found to produce a specific soluble cytotoxic factor which appears to mediate target killing. It also appears that natural killer cell mediated lysis and antibody dependent cell mediated cytotoxicity are properties of one cell type. Natural cytotoxic cells and natural killer cells appear to be part of a heterogeneous cell population which serve as an in vivo antitumor surveillance mechanism.

Studies on the genetic regulation of tumor growth indicate that metastasis of a tumor is controlled both by non-H-2 gene(s) and gene(s) linked to the H-2 region. The rate of growth of a tumor appeared to be influenced by the host's genetic background, while the ability to metastasize required compatibility in the H-2 complex between host and tumor.

APPENDIX E

ESRD Facility Survey Form and Instructions Used for the Period July-December 31, 1980

ESRD FACILITY SURVEY
INSTRUCTIONS FOR COMPLETION OF HCFA FORM 2744

REPORTING RESPONSIBILITY

The ESRD Facility Survey is designed to capture only a limited amount of information concerning each Federally approved renal facility's operation. It is not intended to yield information on the full range of ancillary services or activities, e.g., referrals, graft outcome, etc. These concerns are more appropriately and validly addressed by the network in supplemental requests or through other segments of the Medical Information System.

Every facility/center certified by Medicare to provide services to ESRD patients must furnish the information requested in the ESRD Facility Survey (42 USC 426; 20 CFR 405, Section 2133).

Survey Period

The Facility Survey is completed semiannually. The survey periods are January 1 through June 30, and July 1 through December 31.

This Facility Survey is to be completed for the period January 1, 1981 through June 30, 1981. Unless specified otherwise, all data entered on the Facility Survey is to cover the entire survey period. The form should be completed and forwarded to the local ESRD Network, at the following address:

GENERAL INSTRUCTIONS

For purposes of this document, the word "facility" will be used interchangeably when referring to renal dialysis facilities, renal dialysis centers, or renal transplant centers, as applicable.

All patient and treatment counts requested are to include only the diagnosed chronic ESRD population; no reversible failure patients or treatments may be counted.

All diagnosed chronic ESRD patients treated at the facility should be counted and reported as (1) regular, continuing caseload (field 03); (2) added to the regular caseload (fields 04A through 07B); (3) lost from the regular caseload (fields 08A through 13B); or (4) transient (field 34).

Transient, seasonal, temporary transfers for inpatient care or vacation are reported in two ways. The usual (3 months, 51 percent or more of treatment/supervision) facility counts the patient as part of regular caseload; the facility that treats/supervises the patient episodically (less than 3 months or less than 51 percent) counts the patient (one time only if multiple transfers have occurred) in field 34.

Inclusion of patients in counts should not depend on entitlement determination; newly diagnosed chronic unit admissions should be included, both for peritoneal or hemodialytic therapy and transplantation.

PART ONE

(FOR COMPLETION BY DIALYSIS UNITS ONLY)

I. PATIENT LOAD

Patients Receiving Care Beginning of Survey Period

Field 01: In-Unit. Enter the number of patients dialyzing in your facility at the beginning of the survey period. This number should reflect your "permanent" patient population; that is, those patients for whom your facility had ongoing medical responsibility for the routine care of the patient until he/she was formally transferred elsewhere. Therefore, this number should include those of your routine patients who were hospitalized or were in transient status away from your facility at the beginning of the survey period. (This number should equal the total of fields 36 through 42 from the previous survey submitted.)

Field 02. Home. Enter the number of patients followed by your facility (that is, for whom your facility had the major medical responsibility) who were dialyzing at home (hemodialysis, peritoneal dialysis, or continuous ambulatory peritoneal dialysis) at the beginning of the survey period. (This number should equal the sum of fields 43 through 45 from the previous survey submitted.)

Field 03: Total. Enter the sum of fields 01 and 02. This is to equal the number of patients on your facility's register at the beginning of the survey period. (This number should be the same as that reported in field 46 from the previous survey submitted.

Additions During the Survey Period

NOTE. This section require counts for additional in-unit and home dialysis patients accepted during the survey period. A PATIENT SHOULD NOT BE COUNTED IN MORE THAN ONE FIELD as an addition in fields 04A through 07B. Count them in the field which describes the last status if more than one is applicable.

Newly Diagnosed Patients:

Field 04A: In-Unit--Started for the First Time Ever. Enter the number of newly diagnosed ESRD patients who were admitted to your facility as chronic maintenance dialysis patients for the first time ever during the survey period. This is a count of patients who have begun their initial course of maintenance dialysis therapy at your facility during the survey period. Do not include patients who transferred to your facility from another dialysis facility; that data is to be reported in field 06A.

Field 04B: Home--Started for First Time Ever. Enter the number of newly diagnosed ESRD patients who, after being stabilized on dialysis, successfully completed a course of self-dialysis training and began home dialysis (their initial course of dialysis after training) during the survey period. If they are still in training at the end of the survey period, report them in field 04A.

Restarted Dialysis:

Field 05A: In-Unit--Restarted. Enter the number of patients who restarted in-unit dialysis during the survey period; e.g., persons who had temporarily recovered kidney function, discontinued dialysis, or had been lost to follow-up and have since restarted routine in-unit dialysis.

Field 05B: Home--Restarted. Enter the number of patients who restarted home dialysis during the survey period. These are patients who had temporarily recovered kidney function, discontinued dialysis, or had been lost to follow-up and have since restarted regular home dialysis.

II. Transferred From Another Facility:

Field 06A: In-Unit--Transferred from Other Dialysis Unit. Enter the number of patients admitted to your facility who were formally transferred from another facility during the survey period and who are continuing a regular course of dialysis at your facility.

Field 06B: Home--Transferred from Other Dialysis Unit. Enter the number of home patients who were formally transferred by another facility during the survey period to your unit for ongoing medical supervision and responsibility.

Returned After Transplantation:

NOTE: These fields should include only those patients who had been transplanted during the previous survey period. (Therefore, the patients counted in fields 07A and 07B were not counted in "Patients Remaining at the End of the Survey Period" from the previous survey, and are not counted in "Patients Receiving Care at the Beginning of the Survey Period" for this survey.)

Field 07A: In-Unit--Returned After Transplantation. Enter the number of patients who returned to in-unit dialysis during the survey period after a transplant failure.

Field 07B: Home--Returned After Transplantation. Enter the number of patients who returned to home dialysis during the survey period after a transplant failure.

Losses During the Survey Period

NOTE: These fields describe losses to your facility of both in-center and home dialysis patients that occurred during the survey period. A PATIENT SHOULD NOT BE COUNTED IN MORE THAN ONE FIELD from field 08A through 13B. For purposes of this survey, "in-unit" includes patients who routinely dialyzed in-unit at the time of loss to the reporting facility, and "home" includes patients who routinely dialyzed at home at the time of loss to the reporting facility. Count patients in the field which describes the last status if more than one is applicable.

Deaths:

Field 08A: In-Unit--Deaths. Enter the number of in-unit dialysis patients who died during the survey period. (These deaths must be shown here by the facility if the patients were reported in fields 01, 04A, 05A, 06A, or 07A.)

Field 08B: Home--Deaths. Enter the number of home dialysis patients who died during the survey period. (These deaths must be shown here by the facility if the patients were reported in fields 02, 04B, 05B, 06B, or 07B.)

Recovered Kidney Function:

NOTE: These are diagnosed chronic renal failure patients who recovered renal function.

Field 09A: In-Unit--Recovered Kidney Function. Enter the number of patients who recovered kidney function and ceased chronic ESRD in-unit dialysis during the survey period.

Field 09B: Home--Recovered Kidney Function. Enter the number of patients who recovered kidney function and ceased chronic home ESRD dialysis during the survey period.

Transplanted:

NOTE: Unless a patient who has been transplanted is returned to a regular dialytic regimen by the end of the survey period (graft survival is indeterminate), they should be counted as losses here.

Field 10A: In-Unit--Received Transplant. Enter the number of patients who received a kidney transplant and left the in-unit dialysis program during the survey period.

Field 10B: Home--Received Transplant. Enter the number of patients who received a kidney transplant and left the home dialysis program during the survey period.

Transferred Out:

Field 11A: In-Unit--Transferred to Other Dialysis Unit. Enter the number of in-unit dialysis patients who permanently transferred to another dialysis facility for their ongoing dialysis during the survey period; that is, those patients whose ongoing, routine medical supervision became the responsibility of another dialysis facility.

Field 11B: Home--Transferred to Other Dialysis Unit. Enter the number of home patients who had been followed by your facility but who are now permanently followed by another home dialysis program.

Discontinued Dialysis:

Field 12A: In-Unit Discontinued Dialysis. Enter the number of chronic patients who permanently discontinued dialysis (excluding those reported in fields 08A, 09A, 10A and 11A) who had been dialyzing in-unit during the survey period.

Field 12B: Home--Discontinued Dialysis: Enter the number of chronic patients who permanently discontinued dialysis (excluding those reported in fields 08B, 09B, 10B, and 11B) who had been dialyzing at home during the survey period.

Lost to Follow-Up:

Field 13A: In-Unit--Lost to Follow-Up (LTFU). Enter the number of patients who had been dialyzing in-unit who left your dialysis program during the survey period and whose current status is unknown to your facility (lost to follow-up). Do not include those reported in fields 08A, 09A, 10A, 11A, or 12A.

Field 13B: Home--Lost to Follow-Up (LTFU). Enter the number of patients, followed by your facility, who had been dialyzing at home who were removed from your facility's rolls during the survey period, and whose current status is unknown to your facility (lost to follow-up). Do not include those reported in fields 08B, 09B, 10B, 11B, or 12B.

Patients Receiving Care at the End of the Survey Period

NOTE: DO NOT COUNT A PATIENT IN MORE THAN ONE FIELD. Patients receiving care at the beginning of the survey period plus the additions during the survey period minus the losses during the survey period should equal the patients receiving care (remaining) at the end of the survey period. In terms of the survey form, this means that field 03 plus fields 04A through 07B minus fields 08A through 13B equals field 24.

Staff-Assisted Dialysis:

Field 14: Hemodialysis: Enter the number of patients who, at the end of the survey period, were receiving staff-assisted hemodialysis.

Field 15: Peritoneal Dialysis. Enter the number of patients who, at the end of the survey period, were receiving staff-assisted peritoneal dialysis.

In-Unit Self-Dialysis:

Field 16: Hemodialysis. Enter the number of in-unit self-hemodialysis patients as of the end of the survey period. Self-dialysis training patients are to be reported in field 18.

Field 17: Peritoneal Dialysis. Enter the number of in-unit self-peritoneal dialysis patients as of the end of the survey period. Self-dialysis training patients are to be reported in field 19.

Self-Dialysis Training:

Field 18: Hemodialysis. Enter the number of patients who are in a self-hemodialysis training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to perform their own self-dialysis in-unit or at home.

Field 19: Peritoneal Dialysis.

Enter the number of patients who are in a self-peritoneal dialysis training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to perform their own self-dialysis in-unit or at home.

Field 20: Continuous Ambulatory Peritoneal Dialysis (CAPD) Enter the number of patients who are in a CAPD training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to independently perform CAPD.

Home Dialysis

Field 21: Hemodialysis. Enter the number of patients who hemodialyze at home as of the end of the survey period.

Field 22: Peritoneal Dialysis. Enter the number of patients who are on home peritoneal dialysis as of the end of the survey period.

Field 23: Continuous Ambulatory Peritoneal Dialysis (CAPD). Enter the number of patients who are on CAPD as of the end of the survey period.

Total:

Field 24: Total. Enter the total number of patients on your facility's register at the end of the survey period (the sum of fields 14 through 23 equals field 24).

Patient Eligibility Status--End of Survey Period

NOTE: Fields 25 + 26 + 27 should equal the total number of patients at the facility at the end of the survey period (this should be the same number as that in field 24).

Field 25: Currently Enrolled in Medicare. Enter the number of patients at the end of the survey period who were enrolled in Medicare.

Field 26: Medicare Application Pending. Enter the number of patients at the end of the survey period who had Medicare applications pending.

Field 27: Non-Medicare. Enter the number of patients at the end of the survey period who were not enrolled in Medicare and who did not have Medicare applications pending.

Patients Who Shifted Status During Survey Period:

NOTE: The numbers in fields 28A and 28B reflect patients who changed their dialysis treatment site during the survey period. These numbers are "independent" in the sense that they are not included with the "Additions' (fields 04A through 07B), nor are they included among the "Losses" (fields 08A through 13B).

Field 28A: Shifted Status (In-Unit to Home). Enter the number of patients who, during the survey period, shifted treatment status from in-unit dialysis (staff-assisted or self) to home dialysis.

Field 28B: Shifted Status (Home to In-Unit). Enter the number of patients who, during the survey period, shifted treatment status from home dialysis to in-unit dialysis (staff-assisted or self).

Home/Self-Dialysis Patients Completing Training

NOTE: The following section (fields 29 through 33) should be completed only by those facilities that have self-care training programs. Included in this section will be the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training at the reporting facility which enabled them to self-dialyze in - unit or at home. Patients who were still in a self-dialysis training course on the last day of the survey period are not to be counted in these fields; that data is to be reported in fields 18 through 20. Unsuccessful trainees (those who did not go home or initiate self-care in a facility) are not to be counted here. (This count is a non-add, non-subtract count for caseload purposes.)

Hemodialysis:

Field 29: Home Hemodialysis. Enter the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training for home self-hemodialysis.

Field 30: In-Unit Self-Hemodialysis. Enter the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training for in-unit self-hemodialysis.

Peritoneal Dialysis

Field 31: Home Peritoneal Dialysis. Enter the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training for home self-peritoneal dialysis.

Field 32: In-Unit Self Peritoneal Dialysis. Enter the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training for in-unit self-peritoneal dialysis.

Continuous Ambulatory Peritoneal Dialysis

Field 33: CAPD. Enter the number of patients who, during the survey period, successfully completed an initial course of self-dialysis training for continuous ambulatory peritoneal dialysis.

Transient Patients

Field 34: Transient Patients Treated During Survey Period. Enter the number of transient chronic patients who received care at your facility during the survey period. For purposes of this survey, a transient patient is one who does not intend to utilize the reporting facility for ongoing maintenance therapy. This field is a count of patients, not episodes of treatment. Therefore, if a patient is treated at a facility in February and again at that same facility in March, he/she is counted only once.

Field 35: Transient Patients--Number of Treatments During Survey Period. Using the definition of "transient patient" given above, enter the number of transient patient dialysis treatments (all dialysis settings) given during the survey period.

Dialysis Patients Awaiting Transplant

Field 36: Dialysis Patients Awaiting Transplant. Enter the number of patients dialyzing at your facility or dialyzing at home and followed by your facility who are awaiting transplant as of the last day of the survey period. These patients must: (a) be medically able, (b) have given consent, and (c) be on an active transplant list. This count should include all of your facility's patients who are on a transplant list at any transplant center--counted one time only.

TREATMENT LOAD

NOTE: The following section (fields 37 through 45) should reflect only treatments given to ESRD patients. Self-care training treatments should be reported only in fields 43 through 45. All such treatments, including those provided to transients, should be reported in fields 37 through 45, where appropriate.

Hemodialysis

Field 37: Inpatient Hemodialysis. Enter the number of inpatient hemodialysis treatments given to chronic dialysis patients and to patients pre-and post-transplant during the survey period. Self-care training treatments should not be included here. Also, in some unusual situations, a dialysis facility may, by written arrangement, provide the staff and/or equipment to perform inpatient treatments for chronic patients be reported by one of the facilities.

Field 38: Staff-Assisted Outpatient Treatments. Enter the number of in-unit staff-assisted hemodialysis treatments provided on an outpatient basis during the survey period.

Field 39: In-Unit Self-Care Outpatient Treatments. Enter the number of outpatient hemodialysis treatments performed by in-unit self-dialyzing patients during the survey period.

Peritoneal Dialysis

Field 40: Inpatient Peritoneal Dialysis. Enter the number of inpatient peritoneal dialysis treatments provided to chronic dialysis patients and patients pre- and post-transplant during the survey period. Self-care training peritoneal treatments should not be included here. Also, in some unusual situations, a dialysis facility may, by written arrangement, provide the staff and/or equipment to perform inpatient treatments for chronic patients in hospitals. These treatments should only be reported by one of the facilities.

Field 41: Staff-Assisted Outpatient Treatments. Enter the number of in-unit staff-assisted peritoneal treatments provided on an outpatient basis during the survey period.

Field 42: In-Unit Self-Care Outpatient Treatments. Enter the number of outpatient peritoneal dialysis treatments performed by in-unit self-dialyzing patients during the survey period.

Self-Care Training Treatments

NOTE: These treatment counts should not be included in prior fields 37 through 42.

Field 43: Hemodialysis. Enter the number of hemodialysis training treatments given during the survey period.

Field 44: Peritoneal Dialysis. Enter the number of peritoneal dialysis training treatments given during the survey period.

Field 45: CAPD. Enter the number of CAPD training treatments given during the survey period.

Facility Operation

Hemodialysis

Field 46: Average Patient Shifts Per Week. Enter the average number of hemodialysis patient shifts operated per week during the survey period (rounded to one decimal place). The number of machines operated by the facility is not a factor to be used in computing this figure. Example: 2 patient shifts Monday, Wednesday, and Friday plus 3 patient shifts Tuesday, Thursday, and Saturday = 15.0 patient shifts per week.

Field 47: Average Operating Days per Week. Enter the average number of days per week this facility was in operation for hemodialysis during the survey period (this figure should be rounded to one decimal place).

Peritoneal Dialysis

Field 48: Average Patient Shifts Per Week. Enter the average number of peritoneal dialysis patient shifts operated per week during the survey period (rounded to one decimal place).

Field 49: Average Operating Days Per Week. Enter the average number of days per week this facility was in operation for peritoneal dialysis during the survey period (rounded to one decimal place).

Signatures

Part One of the Facility Survey requires signatures, as follows:

Completed by:

Enter the date completed and the name, title, and telephone number of the person who completed the Facility Survey for your facility. This person should be the individual who the ESRD network of HCFA can contact to discuss any information provided in the Facility Survey.

Verified by:

Enter the date verified and the signature and title of the facility's renal adminstrator.

PART TWO
(FOR COMPLETION BY TRANSPLANT FACILITIES ONLY)

I. PATIENTS/TRANSPLANTS

Field 50: Patients Who Received Transplant at This Facility. Enter the number of patients who received a kidney transplant at your facility during the survey period. If a patient received more than one transplant at your center during the survey period the patient is to be counted only once. (The figure in field 50 should equal the sum of fields 51 + 52 + 53.)

Patient Eligibility Status/of Patients Transplanted During Survey Period. Fields 51-53 refer to those patients actually transplanted during the survey period. The total of fields 51 through 53 equals the same number reported in field 50.

Field 51: Currently Enrolled in Medicare. Enter the number of patients transplanted during the survey period who were enrolled in Medicare.

Field 52: Medicare Application Pending. Enter the number of patients transplanted during the survey period who had Medicare applications pending.

Field 53: Non-Medicare. Enter the number of patients transplanted during the survey period who were not enrolled in Medicare and did not have Medicare applications pending.

Transplants Performed at This Facility:

Field 54: Transplants Performed at This Facility--Living Donor. Enter the number of live donor kidney transplants performed at your center during the survey period.

Field 55: Tranplants Performed at This Facility--Cadaveric Donor. Enter the number of cadaveric donor kidney transplants performed at your center during the survey period.

Field 56: Transplants Performed at This Facility--Total Fields 54 Through 55. Enter the sum of fields 54 and 55.

Patients Awaiting Transplant:

Field 57: Patients Awaiting Transplant--Dialysis. Enter the number of current dialysis patients actively awaiting transplant at your center as of the last day of the survey period. These patients must (a) be medically able, (b) have given consent, and (c) be on an active transplant list. This count is limited to individuals awaiting transplant at the reporting center.

Field 58: Patients Awaiting Transplant--Non-Dialysis. Following the procedures described above, enter the number of non-dialysis patients who are awaiting transplant as of the last day of the survey period. This is to include patients scheduled for transplant who have not yet initiated a regular course of dialysis.

II. CADAVER KIDNEYS

Enter the numbers of cadaver kidneys acquired by your center during the survey period in the appropriate blocks according to their source and disposition. Actual, rather than potential, acquisition is assumed.

Harvested at This Center:

Determine the number of cadaveric kidneys that were harvested at your center during the survey period that were:

Field 59: Transplanted at this center

Field 60: Sent to another center for transplantation

Field 61: Not used (discarded)

Field 62: Total of fields 59 through 61.

Cadaveric kidneys procured outside your center by a procurement team from your center are not to be included in these categories.

Obtained from Another Transplant Center/Organ Procurement Agency:

Determine the number of cadaveric kidneys that were harvested outside your center either at another approved transplant center or through an OPA that were:

Field 63: Transplanted at your center

Field 64: Sent to another center

Field 65: Not used (discarded)

Field 66: Total of fields 63 through 65.

These counts should include, where applicable, any kidneys harvested outside your center by a procurement team from your center.

Obtained from a Non-Tranplant Hospital:

Determine the number of cadaveric kidneys that were harvested outside your center in a hospital not approved by Medicare as a transplant center that were:

Field 67: Tranplanted at your center

Field 68: Sent to another center

Field 69: Not used (discarded)

Field 70: Total of fields 67 through 69.

These counts should include, where applicable, any kidneys harvested outside your center by a procurement team from your center.

Disposition of Cadaver Kidneys:

Cadaver Kidneys Transplanted at This Facility:

Field 71: Should equal the total of fields 59 + 63 + 67. This should be the same number that appears in Field 55.

Cadaveric Kidneys Sent to Another Facility:

Field 72: Should equal the total of fields 60 + 64 + 68.

Cadaveric Kidneys Not Used

Field 73: Should equal the total of fields 61 + 65 + 69.

Signatures

Part Two of the Facility Survey requires signatures, as follows:

Completed by:

Enter the date completed and the name, title, and telephone number of the person who completed the Facility Survey for your facility. This person should be the individual who the ESRD network of HCFA can contact.

Verified by:

Enter the date verified and the signature and title of the facility's renal administrator.

PART THREE

You may include here any remarks or additional information you wish to supply concerning the information furnished on this survey.

APPENDIX F

1980 Transplants By Transplant Center, Within ESRD Network

1980 TRANSPLANTS BY TRANSPLANT CENTER WITHIN ESRD NETWORK

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
1	120010 St Francis Hosp Honolulu HI	96817	2	10	12
	* Network Totals *		2	10	12
2	380009 University Hosp Portland OR	97201	11	68	79
2	500005 Virginia Mason Hosp Seattle WA	98101	17	6	23
2	500008 University of Washington Hosp Seattle WA	98105	10	1	11
2	500027 Swedish Hosp Medical Center Seattle WA	98104	10	10	20
	* Network Totals *		48	85	133
3	050047 Presbyterian Hosp-Pacific Med Ctr San Francisco CA	94115	7	63	70
3	050454 University of Calif Hosps and Clinic San Francisco CA	94122	54	98	152
3	050599 Sacramento Med Ctr-Univ of Calif Sacramento CA	95817	7	26	33
	* Network Totals *		68	187	255
4	050025 University Hosp of San Diego Co San Diego CA	92130	6	18	24

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
4	050069 St Joseph Hosp Hemodialysis Ctr Orange CA	92668	1	6	7
4	050123 Childrens Hosp of Los Angeles Los Angeles CA	90027	2	28	30
4	050245 San Bernardino County Med Center San Bernardino CA	92404	2	21	23
4	050262 UCLA Hosp/Center for the Hlth Sciences Los Angeles CA	90024	12	19	31
4	050327 Loma Linda University Medical Center Loma Linda CA	92354	1	15	16
4	050348 Orange Co Medical Center Orange CA	92668	1	13	14
4	050373 Los Angeles Co/use Medical Center Los Angeles CA	90033	6	12	18
4	050376 Harbor Gen Hosp of Los Angeles Co Torrance CA	90502	4	9	13
4	050502 St Vincents Hosp Los Angeles Ca	90057	30	54	84
4	050625 Cedars-Sinai Medical Center Los Angeles CA	90048	5	7	12
	* Network Totals *		70	202	272
5	060024 Colorado Gen Hosp Denver Co	80220	4	61	65

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
5	460009 University of Utah Hosp Salt Lake City UT	84112	17	15	32
5	46002F VA Hosp Salt Lake City UT	84113	0	7	7
	* Network Totals *		21	83	104
6	030002 Good Samaritan Hosp Phoenix AZ	85006	11	10	21
6	030024 St Josephs Hosp + Medical Center Phoenix AZ	85013	2	0	2
6	03013F VA Hosp Tuscon AZ	85713	8	6	14
6	320001 Bernalillo Co Medical Center Albuquerque NM	87106	7	11	18
	* Network Totals *		28	27	55
7	240004 Regional Kidney Disease Program Minneapolis MN	55414	1	42	43
7	240049 University of Minnesota Hosp Minneapolis MN	55455	69	61	130
7	240061 Rochester Methodist Hosp Rochester MN	55901	24	37	61
	* Network Totals *		94	140	234
8	160058 University of Iowa Hosp + Clinics Iowa City IA	52240	8	77	85

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
8	280088 Bishop Clarkson Mem Hosp Omaha NE	68105	1	45	46
	* Network Totals *		9	122	131
9	170040 University of Kansas Medical Center Kansas City KS	66103	0	16	16
9	170122 St Francis Hosp Wichita KS	67214	0	0	0
9	260014 Barnes Hosp St Louis MO	63110	15	27	42
9	260027 Research Hosp + Medical Center Kansas City MO	64132	0	12	12
9	26009F VA Hosp St Louis MO	63106	10	19	29
9	260101 St Louis Childrens Hosp St Louis MO	63110	4	4	8
9	260138 St Lukes Hospital Kansas City MO	64141	7	18	25
9	260141 Missouri University Hosp Columbia MO	65201	3	21	24
	* Network Totals *		39	117	156
10	040016 University of Arkansas Medical Center Little Rock AR	72201	11	4	15
10	370001 Hillcrest Medical Center Tulsa OK	74104	6	10	16

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
10	370035 Oklahoma Memorial Hospital Oklahoma OK	73105	2	7	9
10	370037 St Anthony Hosp Oklahoma City OK	73102	7	22	29
10	370167 Oklahoma Children S Mem Hosp Oklahoma City OK	73104	2	1	3
	* Network Totals *		28	44	72
11	450015 Dallas County Hospital District Dallas TX	75235	10	61	71
11	450018 University of Texas-Medical Branch Galveston TX	77550	20	38	58
11	450068 Hermann Hosp Houston TX	77030	11	37	48
11	450124 Brackenridge Hosp Austin TX	78701	9	11	20
11	450213 Bexar County Hospital District San Antonio TX	78284	14	21	35
11	450358 The Methodist Hospital Houston TX	77030	8	14	22
	* Network Totals *		72	182	254
12	190005 New Orleans Charity Hospital New Orleans LA	70140	0	0	0
12	190035 Hotel Dieu Hosp New Orleans La	70116	4	1	5

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
12	190098 Louisiana State Univ Hosp Shreveport LA	71103	15	38	53
12	190135 Southern Baptist Hosp New Orleans LA	70115	3	6	9
12	190176 Tulane Medical Center Hosp New Orleans LA	70112	6	37	43
	* Network Totals *		28	82	110
13	520098 University Hosp Madison WI	53706	29	69	98
13	520174 Milwaukee Co Gen Hosp Unit 1 Milwaukee WI	53226	14	67	81
	* Network Totals *		43	136	179
14	230039 Mt Carmel Mercy Hosp Detroit MI	48235	2	30	32
14	230046 University Hosp Ann Arbor MI	48109	14	18	32
14	230053 Henry Ford Hosp Detroit MI	48202	7	22	29
14	230059 St Mary's Hospital-ESRD Unit Grand Rapids MI	49502	4	22	26
14	230076 Hutzel Hosp Detroit MI	48201	3	9	12
14	23011F VA Hosp Ann Arbor MI	48105	0	0	0

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
14	230117 Borgess Hosp Kalamazoo MI	49001	5	8	13
14	230130 Wm Beaumont Hosp Royal Oak MI	48072	3	19	22
14	230132 Hurley Hosp Flint MI	48502	0	7	7
14	230230 E W Sparrow Hosp Lansing MI	48912	0	0	0
14	230240 Childrens Hospital Detroit MI	48201	1	12	13
	* Network Totals *		39	147	186
15	140088 University of Chicago Hosp + Clinics Chicago IL	60637	10	55	65
15	140119 Rush-Presbyterian-St Luke :S Med Ctr Chicago IL	60612	4	7	11
15	140148 Memorial Hosp Springfield IL	62701	5	13	18
15	140150 University of Illinois Hosp Chicago IL	60612	8	33	41
15	140276 Loyola Univ Medical Center Maywood IL	60153	0	8	8
15	140281 Northwestern Mem Hosp Chicago IL	60611	5	17	22
15	140283 Childrens Memorial Hospital Chicago IL	60614	4	5	9
	* Network Totals *		36	138	174

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
16	15003F VA Hosp Indianapolis IN	46202	2	2	4
16	150032 Indiana University Hospitals Indianapolis IN	46202	24	25	49
16	150056 Methodist Hosp of Indiana Indianapolis IN	46202	4	20	24
	* Network Totals *		30	47	77
17	180040 Jewish Hosp Louisville KY	40202	13	28	41
17	180067 University of Kentucky Medical Center Lexington KY	40506	12	16	28
17	360003 Cincinnati Gen Hosp Cincinnati OH	45267	16	21	37
17	360051 Miami Valley Hosp Dayton OH	45409	5	15	20
17	360163 Christ Hosp Cincinnati OH	45219	4	12	16
17	360226 Children's Hospital Med Ctr Cincinnati OH	45229	1	14	15
	* Network Totals *		51	106	157
18	010033 University of Alabama Hosps + Clinics Birmingham AL	35294	55	61	116
18	250001 University Hosp Jackson MS	39216	2	8	10

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
18	440039 Vanderbilt University Hosp Nashville TN	32732	30	54	84
18	440166 University of Tennessee Hospital Memphis TN	38103	16	31	47
	* Network Totals *		103	154	257
19	100007 Florida Hosp Orlando FL	32803	2	21	23
19	100022 Jackson Memorial Hospital Miami Florida	33136	24	8	32
19	100113 Shands Teaching Hosp + Clinics Gainesville FL	32610	26	38	64
19	100128 Tampa Gen Hosp Tampa FL	33606	8	36	44
	* Network Totals *		60	103	163
20	110010 Emory University Hosp Atlanta GA	30322	16	37	53
20	110034 Eugene Talmadge Mem Hosp Augusta GA	30902	6	7	13
20	110079 Grady Mem Hosp Atlanta GA	30303	0	7	7
20	420004 Medical College Hosp Charleston SC	29403	8	22	30
	* Network Totals *		30	73	103
21	340030 Duke University Medical Center Durham NC	27706	13	23	36

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
21	340047 North Carolina Baptist Hosp Winston Salem NC	27103	2	9	11
21	340061 North Carolina Mem Hosp Chapel Hill NC	27515	5	15	20
21	340113 Charlotte Mem Hosp + Med Ctr Charlotte NC	28203	1	20	21
	* Network Totals *		21	67	88
22	360015 Akron City Hosp Akron OH	44309	3	16	19
22	360048 Medical College of Ohio at Toledo Toledo OH	43614	4	27	31
22	360085 University Hosp Columbus OH	43210	24	39	63
22	360137 University Hosp Cleveland OH	44106	9	26	35
22	360180 Cleveland Clinic Hosp Cleveland OH	44106	20	50	70
22	390164 Presbyterian-University Hosp Pittsburgh PA	15213	2	45	47
	* Network Totals *		62	203	265
23	090001 George Washington Hosp Washington DC	20037	2	18	20
23	090003 Howard University Hosp Washington DC	20060	4	13	17

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
23	090004 Georgetown Hosp Washington DC	20007	13	15	28
23	090011 Washington Hosp Center Washington DC	20010	6	15	21
23	090014 Childrens Hosp National Medical Center Washington DC	20010	0	4	4
	* Network Totals *		25	65	90
24	390051 Hahnemann Medical College + Hosp Philadelphia PA	19102	9	30	39
24	390111 University of Pennsylvania Hosp Philadelphia PA	19104	40	48	88
24	390142 Albert Einstein Medical Center Philadelphia PA	19141	4	12	16
24	390174 Thomas Jefferson University Hosp Philadelphia PA	19107	3	18	21
24	390259 St Christophers Hosp for Children Philadelphia PA	19133	4	7	11
	* Network Totals *		60	115	175
25	330012 Presbyterian Hosp New York NY	10032	7	14	21
25	330024 Mt Sinai Hosp New York NY	10029	5	13	18
25	330059 Montefiore Hosp Bronx NY	10467	2	38	40

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
25	330101 New York Hosp New York NY	10021	8	45	53
25	330120 St Lukes Hosp Center New York NY	10025	1	21	22
25	330350 Downstate Medical Center Brooklyn NY	11203	21	85	106
	* Network Totals *		44	216	260
26	330005 Buffalo Gen Hosp Buffalo NY	14203	8	30	38
26	330013 Albany Medical Center Hosp Albany NY	12208	2	34	36
26	330219 Erie County Medical Center Buffalo NY	14215	0	13	13
26	330241 State Univ Hosp-Upstate Medical Center Syracuse NY	13210	9	22	31
26	330285 Strong Mem Hospital Rochester NY	14642	9	18	27
	* Network Totals *		28	117	145
27	070022 Yale-New Haven Hosp New Haven CT	06504	8	10	18
27	070025 Hartford Hosp Hartford CT	06115	10	25	35
	* Network Totals *		18	35	53

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
28	200009 Maine Medical Center Portland ME	04101	6	20	26
28	220031 University Hosp Boston MA	02118	2	9	11
28	220071 Massachusetts Gen Hosp Boston MA	02114	12	39	51
28	220086 Beth Israel Hosp Boston MA	02215	3	12	15
28	220110 Peter Bent Brigham Hosp Boston MA	02115	16	26	42
28	220116 New England Medical Center Hosp Boston MA	02111	3	10	13
28	220118 New England Deaconess Hosp Boston MA	02215	7	24	31
28	220122 Childrens Hosp Medical Center Boston MA	02115	7	11	18
28	470003 Vermont Medical Center Hosp Burlington VT	05401	3	16	19
	* Network Totals *		59	167	226
29	40003F VA Hosp Rio Piedras PR	00936	16	2	18
	* Network Totals *		16	2	18
30	490007 Medical Center Hosps-Norfolk Gen Div Norfolk VA	23507	3	27	30

Network	Provider Identification Number Provider Name City, State	Zip	Living	Cadaveric	Total
30	490009 University of Virginia Hosp Charlottesville VA	22903	3	21	24
30	490032 Virginia Hosp Medical College Richmond VA	23298	4	37	41
30	49010F VA Hosp Richmond VA	23249	1	21	22
	* Network Totals *		11	106	117
31	210002 University Hosp Baltimore MD	21201	7	19	26
31	210009 Johns Hopkins Hosp Baltimore MD	21205	10	35	45
31	210029 Baltimore City Hosp Baltimore MD	21224	11	12	23
	* Network Totals *		28	66	94
32	310002 Newark Beth Israel Hosp Newark NJ	07112	2	36	38
32	310029 Our Lady of Lourdes Hosp Camden NJ	08103	2	16	18
32	310076 St Barnabas Medical Center Livingston NJ	07039	0	26	26
	* Network Totals *		4	78	82
* * * *	NATIONAL	TOTALS	1,275	3,422	4,697

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